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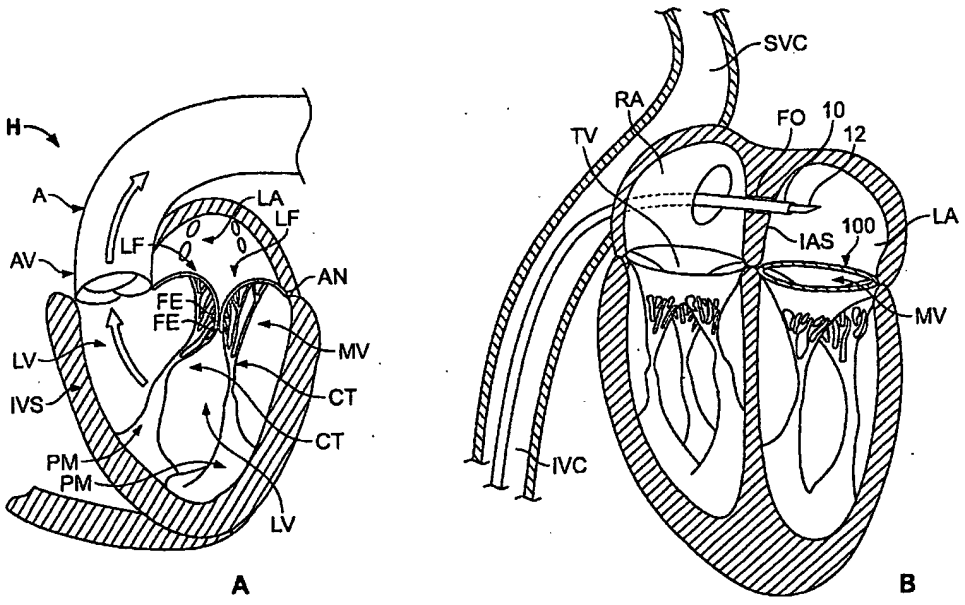

(57) Abstract: Disclosed are methods, systems, and devices for the endovascular repair of cardiac valves, particularly the atrioventricular valves which inhibit back flow of blood from a heart ventricle during contraction. The procedures described herein can be performed with interventional tools, guides and supporting catheters and other equipment introduced to the heart chambers from the patient's arterial or venous vasculature remote from the heart. The interventional tools and other equipment may be introduced percutaneously or may be introduced via a surgical cut down, and then advanced from the remote access site through the vasculature until they reach the heart.

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METHODS, SYSTEMS AND DEVICES FOR CARDIAC VALVE REPAIR

BACKGROUND

[0001] The present invention relates generally to medical methods, devices, and systems. In particular, the present invention relates to methods, devices, and systems for the endovascular or minimally invasive surgical repair of the atrioventricular valves of the heart, particularly the mitral valve.

[0002] Mitral valve regurgitation is characterized by retrograde flow from the left ventricle of a heart through an incompetent mitral valve into the left atrium. During a normal cycle of heart contraction (systole), the mitral valve acts as a check valve to prevent flow of oxygenated blood back into the left atrium. In this way, the oxygenated blood is pumped into the aorta through the aortic valve. Regurgitation of the valve can significantly decrease the pumping efficiency of the heart, placing the patient at risk of severe, progressive heart failure.

[0003] Mitral valve regurgitation can result from a number of different mechanical defects in the mitral valve. The valve leaflets, the valve chordae which connect the leaflets to the papillary muscles, or the papillary muscles themselves may be damaged or otherwise dysfunctional. Commonly, the valve annulus may be damaged, dilated, or weakened limiting the ability of the mitral valve to close adequately against the high pressures of the left ventricle. In some cases the mitral valve leaflets detach from the chordae tendinae, the structure that tethers them to the ventricular wall so that they are positioned to coapt or close against the other valve leaflet during systole. In this case, the leaflet "flails" or billows into the left atrium during systole instead of coapting or sealing against the neighboring leaflet

allowing blood from the ventricle to surge into the left atrium during systole. In addition, mitral valve disease can include functional mitral valve disease which is usually characterized by the failure of the mitral valve leaflets to coapt due to an enlarged ventricle, or other impediment to the leaflets rising up far enough toward each other to close the gap or seal against each other during systole.

[0004] The most common treatments for mitral valve regurgitation rely on valve replacement or strengthening of the valve annulus by implanting a mechanical support ring or other structure. The latter is generally referred to as valve annuloplasty. A recent technique for mitral valve repair which relies on suturing adjacent segments of the opposed valve leaflets together is referred to as the "bow-tie" or "edge-to-edge" technique. While all these techniques can be very effective, they usually rely on open heart surgery where the patient's chest is opened, typically via a sternotomy, and the patient placed on cardiopulmonary bypass. The need to both open the chest and place the patient on bypass is traumatic and has associated morbidity.

SUMMARY

[0005] For the foregoing reasons, it would be desirable to provide alternative and additional methods, devices, and systems for performing the repair of mitral and other cardiac valves, including the tricuspid valve, which is the other atrioventricular valve. In some embodiments of the present invention, methods and devices may be deployed directly into the heart chambers via a trans-thoracic approach, utilizing a small incision in the chest wall, or the placement of a cannula or a port. In other embodiments, such methods, devices, and systems may not require open chest access and be capable of being performed endovascularly, i.e., using devices which are advanced to the heart from a point in the patient's vasculature

remote from the heart. Still more preferably, the methods, devices, and systems should not require that the heart be bypassed, although the methods, devices, and systems should be useful with patients who are bypassed and/or whose heart may be temporarily stopped by drugs or other techniques. At least some of these objectives will be met by the inventions described hereinbelow.

[0006] In one aspect, there is disclosed a method of treating a heart, comprising attaching a first device to a first location of a wall of a left ventricle of the heart; attaching a second device to a second location of the heart, wherein the second location is located opposite the first location; and moving the first device and the second device toward one another to cause the first location and second location to move toward one another so as to re-shape at least one of the mitral valve annulus or the left ventricle in a manner that reduces backflow through the mitral valve.

[0007] In another aspect, there is disclosed a method of treating a heart, comprising coupling at least one valve to a steerable delivery device; percutaneously introducing the valve into the heart using the steerable delivery device; and placing the valve in a pulmonary vein of the heart, wherein the valve regulates blood flow into the left ventricle of the heart.

[0008] In another aspect, there is disclosed a method of treating a heart, comprising coupling a first wedge-shaped device to a steerable delivery device, wherein the first device has a contact surface adapted to be positioned adjacent a first mitral valve leaflet of the heart; percutaneously introducing the first device into the heart using the steerable delivery device; and securing the first device to the

heart such that the first mitral valve leaflet is positioned adjacent the contact surface of the device.

[0009] In another aspect, there is disclosed a device for treating heart disease comprising a prosthetic comprising a wedge having a length that is about equal to a length of a line of coaptation of a mitral valve and a depth sufficient to prevent prolapse of a mitral valve when the wedge is placed atop an annulus of the mitral valve along the line of coaptation; and one or more anchors protruding from the wedge for coupling the wedge to the annulus of the mitral valve.

[0010] Other features and advantages should be apparent from the following description of various embodiments, which illustrate, by way of example, the principles of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Figure 1A is a schematic illustration of the left ventricle of a heart showing blood flow during systole with arrows.

[0012] Figure 1B shows a cross-sectional view of the heart wherein a flexible stent is positioned at or near the mitral valve.

[0013] Figure 2A shows a cross-sectional view of the heart showing one or more magnets positioned around the annulus of the mitral valve.

[0014] Figure 2B shows an annular band with magnets that can be positioned on the mitral valve annulus.

[0015] Figure 3 shows a cross-sectional view of the heart identifying locations for placement of valves.

[0016] Figure 4 show a cross-sectional view of the heart with a pair of flaps mounted at or near the mitral valve.

[0017] Figure 5A shows a schematic side view of the mitral valve leaflets with a flap positioned immediately below each leaflet.

[0018] Figure 5B shows a downward view of the mitral valve with a pair of exemplary flaps superimposed over the leaflets.

[0019] Figure 5C shows a pair of mitral valve leaflet flaps having complementary shapes.

[0020] Figure 6A shows a cross-sectional view of the heart with a membrane ring positioned at the mitral valve annulus.

[0021] Figure 6B shows a schematic view of the membrane ring, which includes an annular ring on which is mounted a membrane.

[0022] Figure 7A shows a cross-sectional view of a heart with a bladder device positioned partially within the left ventricle and partially within the left atrium.

[0023] Figure 7B shows a schematic side view of the mitral valve leaflets failing to coapt.

[0024] Figure 7C shows a schematic side view of a the mitral valve leaflets with a bladder positioned between the leaflets.

[0025] Figure 7D shows a plan view of the mitral valve with the leaflets in an abnormal closure state such that a gap is present between the leaflets.

[0026] Figure 8 shows a cross-sectional view of the heart wherein a one-way valve device is located in the left atrium.

[0027] Figure 9A shows a prosthetic ring that is sized to fit within a mitral valve.

[0028] Figure 9B shows another embodiment of a prosthetic ring wherein a one-way valve is positioned inside the ring.

[0029] Figure 10 shows a prosthetic with one or more tongues or flaps that are configured to be positioned adjacent the flaps of the mitral valve

[0030] Figure 11A shows an exemplary embodiment of one or more clips that are positioned on free edges of the leaflets.

[0031] Figure 11B shows pair of leaflets with a magnetic clip attached to the underside of each leaflet.

[0032] Figure 11C shows the leaflets coapted as a result of the magnetic attraction between the magnetic clips.

[0033] Figure 11D shows a pair of leaflets with a single clip attached to one of the leaflets.

[0034] Figure 12 shows a schematic, cross-sectional view of the heart with a wedge positioned below at least one of the leaflets of the mitral valve.

[0035] Figure 13A shows an artificial chordae tendon.

[0036] Figures 13B and 13C show attachment devices for attaching the artificial chordae tendon to a heart wall.

[0037] Figure 14 shows a cross-sectional view of the heart with a first and second anchor attached to a wall of the heart.

[0038] Figure 15 shows a catheter that has been introduced into the heart.

[0039] Figure 16 shows a schematic view of a papillary muscle with a ring positioned over the muscle.

[0040] Figure 17 shows a cross-sectional view of the heart with one or more magnets attached to a wall of the left ventricle.

[0041] Figure 18A shows another embodiment of a procedure wherein magnets are implanted in the heart to geometrically reshape the annulus or the left ventricle.

[0042] Figure 18B shows the heart wherein tethered magnets are implanted in various locations to geometrically reshape the annulus or the left ventricle.

[0043] Figure 18C shows the heart wherein magnets are implanted in various locations to geometrically reshape the annulus or the left ventricle.

[0044] Figure 19 shows another embodiment of a procedure wherein magnets are implanted in the heart to geometrically reshape the annulus or the left ventricle.

[0045] Figure 20 shows a cross-sectional view of the left ventricle with a tether positioned therein.

[0046] Figure 21 shows a cross-sectional view of the left ventricle with a delivery catheter positioned therein.

[0047] Figure 22 shows a cross-sectional view of the left ventricle with the delivery catheter penetrating a wall of the left ventricle.

[0048] Figure 23 shows a cross-sectional view of the left ventricle with the delivery catheter delivering a patch to the wall of the left ventricle.

[0049] Figure 24 shows a cross-sectional view of the left ventricle with the delivery penetrating delivering a second patch.

[0050] Figure 25 shows a cross-sectional view of the left ventricle with two tethers attached together at opposite ends from the patches mounted in the heart.

[0051] Figure 26 shows a cross-sectional view of the left ventricle with a needle or delivery catheter passed transthoracicaly into the left ventricle LV to deliver a patch to the exterior of the ventricular wall.

[0052] Figure 27 shows a schematic, cross-sectional view of the left ventricle in a healthy state with the mitral valve closed.

[0053] Figure 28 shows the left ventricle in a dysfunctional state.

[0054] Figure 29 shows the left ventricle with a biasing member mounted between the papillary muscles.

[0055] Figure 30 shows the left ventricle with a suture mounted between the papillary muscles.

[0056] Figure 31 shows the left ventricle with a snare positioned around the chordae at or near the location where the chordae attach with the papillary muscles.

[0057] Figure 32 shows a leaflet grasping device that is configured to grasp and secure the leaflets of the mitral valve.

[0058] Figures 33A-33C show the leaflet grasping device grasping leaflets of the mitral valve.

[0059] Figure 34 shows the left ventricle with a needle being advanced from the left atrium into the left ventricle via the leaflet grasping device.

[0060] Figure 35 shows the left ventricle with sutures holding the papillary muscles in a desired position.

[0061] Figure 36 shows a cross-sectional view of the heart with one or more clips clipped to each of the papillary muscles.

[0062] Figure 37 shows a cross-sectional view of the heart with tethered clips attached to opposed walls of the left ventricle.

DETAILED DESCRIPTION

[0063] The present invention provides methods, systems, and devices for the endovascular repair of cardiac valves, particularly the atrioventricular valves which inhibit back flow of blood from a heart ventricle during contraction (systole), most particularly the mitral valve between the left atrium and the left ventricle. By "endovascular," it is meant that the procedure(s) of the present invention are performed with interventional tools, guides and supporting catheters and other equipment introduced to the heart chambers from the patient's arterial or venous vasculature remote from the heart. The interventional tools and other equipment may

be introduced percutaneously, i.e., through an access sheath, or may be introduced via a surgical cut down, and then advanced from the remote access site through the vasculature until they reach the heart. Thus, the procedures of the present invention will generally not require penetrations made directly through the exterior heart muscle, i.e., myocardium, although there may be some instances where penetrations will be made interior to the heart, e.g., through the interatrial septum to provide for a desired access route.

[0064] While the procedures of the present invention will usually be percutaneous and intravascular, many of the tools will find use in minimally invasive and open surgical procedures as well that includes a surgical incision or port access through the heart wall. In particular, the tools for capturing the valve leaflets prior to attachment can find use in virtually any type of procedure for modifying cardiac valve function.

[0065] The atrioventricular valves are located at the junctions of the atria and their respective ventricles. The atrioventricular valve between the right atrium and the right ventricle has three valve leaflets (cusps) and is referred to as the tricuspid or right atrioventricular valve. The atrioventricular valve between the left atrium and the left ventricle is a bicuspid valve having only two leaflets (cusps) and is generally referred to as the mitral valve. In both cases, the valve leaflets are connected to the base of the atrial chamber in a region referred to as the valve annulus, and the valve leaflets extend generally downwardly from the annulus into the associated ventricle. In this way, the valve leaflets open during diastole when the heart atria fill with blood, allowing the blood to pass into the ventricle.

[0066] During systole, however, the valve leaflets are pushed together and closed to prevent back flow of blood into the atria. The lower ends of the valve leaflets are connected through tendon-like tissue structures called the chordae, which in turn are connected at their lower ends to the papillary muscles. Interventions according to the present invention may be directed at any one of the leaflets, chordae, annulus, or papillary muscles, or combinations thereof. It will be the general purpose of such interventions to modify the manner in which the valve leaflets coapt or close during systole so that back flow or regurgitation is minimized or prevented.

[0067] The left ventricle LV of a normal heart H in systole is illustrated in Figure 1A. The left ventricle LV is contracting and blood flows outwardly through the tricuspid (aortic) valve AV in the direction of the arrows. Back flow of blood or "regurgitation" through the mitral valve MV is prevented since the mitral valve is configured as a "check valve" which prevents back flow when pressure in the left ventricle is higher than that in the left atrium LA. The mitral valve MV comprises a pair of leaflets having free edges FE which meet evenly to close, as illustrated in Figure 1A. The opposite ends of the leaflets LF are attached to the surrounding heart structure along an annular region referred to as the annulus AN. The free edges FE of the leaflets LF are secured to the lower portions of the left ventricle LV through chordae tendineae CT (referred to hereinafter as the chordae) which include plurality of branching tendons secured over the lower surfaces of each of the valve leaflets LF. The chordae CT in turn, are attached to the papillary muscles PM which extend upwardly from the lower portions of the left ventricle and interventricular septum IVS.

[0068] While the procedures of the present invention will be most useful with the atrioventricular valves, at least some of the tools described hereinafter may be useful in the repair of other cardiac valves, such as peripheral valves or valves on the venous side of the cardiac circulation, or the aortic valve.

[0069] The methods of the present invention can comprise accessing a patient's vasculature at a location remote from the heart, advancing an interventional tool through the vasculature to a ventricle and/or atrium, and engaging the tool against a tissue structure which forms or supports the atrioventricular valve. By engaging the tool against the tissue structure, the tissue structure is modified in a manner that reduces valve leakage or regurgitation during ventricular systole. The tissue structure may be any of one or more of the group consisting of the valve leaflets, chordae, the valve annulus, and the papillary muscles, atrial wall, ventricular wall or adjacent structures. Optionally, the interventional tool will be oriented relative to the atrioventricular valve and/or tissue structure prior to engaging the tool against the tissue structure. The interventional tool may be self-orienting (e.g., pre-shaped) or may include active mechanisms to steer, adjust, or otherwise position the tool.

[0070] Alternatively, orientation of the interventional tool may be accomplished in whole or in part using a separate guide catheter, where the guide catheter may be pre-shaped and/or include active steering or other positioning means such as those devices set forth in United States Patent Application Serial Numbers 10/441,753 filed May 19, 2003, 10/441,508 filed May 19, 2003 and 10/441,687 filed May 19, 2003, all of which are expressly incorporated by reference herein. In all cases, it will usually be desirable to confirm the position prior to engaging the valve leaflets or other tissue structures. Such orienting step may comprise positioning the tool relative to a line of coaptation in the atrioventricular

valve, e.g., engaging positioning elements in the valve commissures and confirming the desired location using a variety of imaging means such as magnetic resonant imaging (MRI), intracardiac echocardiography (ICE), transesophageal echo (TEE), fluoroscopy, endoscopy, intravascular ultrasound (IVUS) and the like.

[0071] In some embodiments, heart disease in general, and valve repair in particular, are treated by targeting the pacing of the heartbeat. In one embodiment, heart disease is treated by introducing one or more pacing leads into a heart chamber. The pacing leads are placed in contact with a heart muscle and are in electrical communication with a power source. The power source provides paced electrical stimuli to the heart muscle. The electrical stimuli are provided during or immediately after systole to extend systolic contraction of the heart, thereby extending the range of systole during each heartbeat. This extension of systole extends the amount of time in which the heart muscle tightens when it would otherwise be relaxing, when there is most mitral regurgitation in diseased mitral valves.

[0072] Other embodiments are directed to annuloplasty to treat heart disease in general and valve repair in particular. In one embodiment, shown generally in Figure 1B, a stent is used to treat the mitral valve. Figure 1B shows a cross-sectional view of the heart wherein a flexible stent 100 is positioned at or near the mitral valve MV. The stent 100 is annular and is sized and shaped to be positioned on the annulus of the mitral valve. The stent 100 can transition between a collapsed state of reduced size and an expanded state of enlarged size relative to the collapsed state.

[0073] The flexible stent 100 can be percutaneously introduced into an individual's heart while being biased toward the collapsed state. The stent is advanced partially through the annulus of the mitral valve so that it is coaxially positioned within the annulus, as shown in Figure 1B. The stent 100 is then secured to the annulus such that the stent exerts an inward force on the annulus thereby causing the annulus to resist dilation during diastole of the heart.

[0074] In yet another embodiment, a device is disclosed for treating the mitral valve. The device can be a stent, such as the stent 100, that is sized to fit coaxially within an annulus of a mitral valve. The stent includes a hollow frame. The frame can be annular such that it has a cross-sectional diameter that is sized such that an outer surface of the frame is in continuous coaxial contact with the annulus. The frame also includes one or more anchors protruding from it for securing the stent to the annulus. The anchors can be prongs, barbs, protrusions, or any structure adapted to secure the stent to the annulus. The stent is flexible between an expanded configuration and a contracted configuration and is biased toward the contracted configuration so that it exerts an inward force on the annulus.

[0075] In one embodiment, the stent 100 is delivered using a delivery catheter 10 that is advanced from the inferior vena cava IVC into the right atrium RA. Once the catheter 10 reaches the anterior side of the interatrial septum IAS, a needle 12 may be advanced so that it penetrates through the septum at the fossa ovalis FO or the foramen ovale into the left atrium LA. At this point, a delivery device can be exchanged for the needle and the delivery device used to deliver the stent 100. The catheter 10 can also approach the heart in other manners.

[0076] Figure 2A shows a cross-sectional view of the heart showing one or more magnets 210 positioned around the annulus of the mitral valve MV. A corresponding method of treating heart disease involves the use of magnets. The method includes percutaneously introducing at least a first magnet 205 into an individual's heart and securing it to the mitral valve MV annulus. At least a second magnet 210 is percutaneously introduced into the heart and advanced so that it is within a magnetic field of the first magnet. The second magnet is secured to the heart. The polarity of one of the two magnets is then cyclically changed in synchronization with the heart beat so that the magnets attract and repel each other in synchronization with the heart beat. The first magnet therefore moves in relation to the second magnet and exerts an inward closing force on the mitral valve during systole. The magnets 210 can be positioned on an annular band 215 (shown in Figure 2B) that is sized and shaped to be implanted on the annulus of the mitral valve. The band 215 can be, for example, a stent.

[0077] In one embodiment, the magnets 210 or the annular band 215 are delivered using a delivery catheter 10 that is advanced from the inferior vena cava IVC into the right atrium RA, as described above with reference to Figure 1. Any of the devices described herein can be percutaneously delivered into the heart by coupling the device to a delivery device, such as a steerable delivery catheter.

[0078] In yet another embodiment involving magnets, two or more magnets are percutaneously introduced into an individual's coronary sinus such that they attract or repel each other to reshape the coronary sinus and an underlying mitral valve annulus.

[0079] Other embodiments involve various prosthetics for treating heart disease in general and defective or diseased mitral valves in particular. In one embodiment, a method of treatment includes placing one or more one-way valves in one or more pulmonary veins of an individual either near the ostium of the vein or at some point along the length of the PV. Valves that may be used, for example may be stentless valves such as designs similar to the TORONTO SPV® (Stentless Porcine Valve) valve, mechanical or tissue heart valves or percutaneous heart valves as are known in the art provided they are sized appropriately to fit within the lumen of the pulmonary vein, as shown in Figure 3. In Figure 3, the locations in the left atrium LA where valves can be positioned in pulmonary vein orifices are represented by an "X". In addition, certain venous valve devices and techniques may be employed such as those described in United States Patent, 6,299,637 and 6,585,761, and United States Patent Applications 20040215339 and 20050273160, the entire contents of which are incorporated herein by reference. A valve prosthesis for placement in the ostia of the pulmonary vein from the left atrium may be in the range of 6-20mm in diameter. Placement of individual valves in the pulmonary vein ostia (where the pulmonary veins open or take off from the left atrium) may be achieved by obtaining trans septal access to the left atrium with a steerable catheter, positioning a guidewire through the catheter and into the targeted pulmonary vein, and deploying a valve delivery catheter over the guidewire and deploying the valve out of the delivery catheter. The valve may be formed of a deformable material, such as stainless steel, or of a self-expanding material such as NiTi, and include tissue leaflets or leaflets formed of a synthetic material, such as is known in the art. A line of +++++ symbols in Figure 3 represents a mid-atrial location above the mitral valve where a single valve can be positioned as disclosed later in this specification.

[0080] The following references, all of which are expressly incorporated by reference herein, describe devices (such as steerable catheters) and methods for delivering interventional devices to a target location within a body: United States Patent Application Serial Numbers 10/441,753 filed May 19, 2003, 10/441,508 filed May 19, 2003 and 10/441,687 filed May 19, 2003.

[0081] Figure 4 show a cross-sectional view of the heart with a pair of flaps mounted at or near the mitral valve. Figure 5A shows a schematic side view of the mitral valve leaflets LF with a flap 300 positioned immediately below each leaflet. The flap 300 can be contoured so as to conform at least approximately to the shape of a leaflet, or the flap 300 can be straight as shown in Figure 4. Figure 5B shows a downward view of the mitral valve with a pair of exemplary flaps superimposed over the leaflets LF. As shown in Figure 5C, the flaps can have complementary shapes with a first flap having a protrusion that mates with a corresponding recess in a second flap.

[0082] In corresponding method of treatment, shown in Figures 4 and 5C, a first flap 300 with an attachment end 305 and a free end 310 is provided. The attachment end 305 of the first flap 300 is secured to the inside wall of the ventricle below the mitral valve. A second flap 315 with an attachment end 320 and a free end 330 is provided and is also secured to the inside wall of the ventricle below the mitral valve. The first and second flaps 300, 315 are oriented so that they face each other and the free ends 310, 330 are biased toward each other and approximate against each other during systole. This system provides a redundant valving system to assist the function of the native mitral valve.

[0083] In other embodiments, devices and methods that involve prosthetic discs are disclosed. For example, Figure 6A shows a cross-sectional view of the heart with a membrane ring 610 positioned at the mitral valve annulus. Figure 6B shows a schematic view of the membrane ring 610, which includes an annular ring on which is mounted a membrane. The membrane includes a series of perforations 615 extending through the membrane surface. One or more anchor devices, such as prongs, can be located on the ring for securing the ring to the mitral valve.

[0084] In one embodiment, a device for treating heart disease in general and defective or diseased mitral valves in particular includes a disc having a ring, a membrane stretched across an opening of the ring, and one or more anchors for securing the disc to an annulus of a mitral valve. The disc is sized to cover the annulus of the mitral valve, and the membrane includes one or more perforations that permit one way fluid flow through the disc. Methods of treatment using the device are also provided.

[0085] In other embodiments, devices and methods that involve fluid-filled bladders are disclosed. Figure 7A shows a cross-sectional view of a heart with a bladder device positioned partially within the left ventricle and partially within the left atrium. A device for treating heart disease in general and defective or diseased mitral valves in particular includes a fluid-filled bladder 600. The bladder 600 is placed across the mitral valve between the left atrium and the left ventricle. Upon compression of the left ventricle, the volume of the bladder is expanded on the left atrial side of the heart, providing a baffle or sealing volume to which the leaflets of the mitral valve coapt. The bladder may also act as a blocking device in the case of flail of a leaflet, blocking said flailing leaflet from billowing into the left atrium causing regurgitation. The bladder also includes one or more anchors for securing the

bladder to an annulus of a mitral valve, or may be formed on a cage or other infrastructure to position it within the line of coaptation of the mitral valve.

[0086] A bladder can also be used to treat functional mitral valve disease. As mentioned, functional mitral valve disease is usually characterized by the failure of the mitral valve leaflets to coapt due to an enlarged ventricle, or other impediment to the leaflets rising up far enough toward each other to close the gap or seal against each other during systole. Figure 7B shows a schematic side view of the mitral valve leaflets LF failing to coapt such that regurgitation can occur (as represented by the arrow RF.) With reference to Figure 7C, a baffle or bladder 630 is positioned between the leaflets LF along the line of coaptation of the leaflets. The bladder 630 provides a surface against which at least a portion of the leaflets LF can seal against. The bladder 630 thus serves as a coaptation device for the leaflets. The bladder can be attached to various locations adjacent to or on the mitral valve. Figure 7D shows a plan view of the mitral valve with the leaflets LF in an abnormal closure state such that a gap G is present between the leaflets. In one embodiment, the bladder is attached or anchored to the mitral valve at opposite edges E of the gap G.

[0087] Methods of treatment using the bladder include providing the bladder and inserting it through an annulus of a mitral valve such that the bladder is coaxially positioned through the mitral valve. An atrial portion of the bladder extends into the left atrium, and a ventricular portion of the bladder extends into the left ventricle. A mid portion of the bladder may be secured to the annulus of the mitral valve such that the mid portion remains stationery while the atrial and ventricular portions expand and contract passively between the atrium and ventricle based on pressure differentials during systole and diastole.

[0088] Figure 8 shows a cross-sectional view of the heart wherein a one-way valve device 700 is located in the left atrium. The valve device is represented schematically in Figure 8. A corresponding method of treating heart disease includes introducing a one-way valve device 700 into the left atrium of an individual's heart proximal the mitral valve. The valve device 700 is configured to permit fluid flow in one direction while preventing fluid flow in an opposite direction. The valve device can have various structures. For example, the device can comprise a valve that is mounted on a stent that is sized to be positioned in the left atrium. Valves that may be used, for example may be stentless valves such as the TORONTO SPV® (Stentless Porcine Valve) valve, mechanical or tissue heart valves or percutaneous heart valves as are known in the art. The outer wall of the one-way valve device is sealed to the inner wall of the atrium so that a fluid-tight seal is formed between the outer wall of the one-way valve device and the inner wall of the left atrium. In this regard, the valve device can include a seal member that is configured to seal to the inner wall of the atrium.

[0089] Another embodiment involves a prosthetic for treating heart disease in general and defective or diseased mitral valves in particular. Figure 9A shows a prosthetic ring 800 that is sized to fit within a mitral valve annulus The ring includes one or more anchors 805 that extend around the periphery of the ring 800. In addition, one or more struts 810 struts extend across the diameter of the ring, and can be made of a material that includes nitinol or magnetic wires for selectively adjusting the shape of the ring. The struts can also be instrumental in baffling mitral valve leaflet "flail". Figure 9B shows another embodiment of a prosthetic ring 807 wherein a one-way valve 815 is positioned inside the ring such that blood flow BF

can flow through the valve in only one direction. The valve can be manufactured of various materials, such as silicone.

[0090] Figure 10 shows a prosthetic with one or more tongues or flaps that are configured to be positioned adjacent the flaps of the mitral valve. The prosthetic includes a ring 900 sized to fit within a mitral valve annulus. At least two tongues 910 project from the ring 900 in a caudal direction when the ring is implanted into a heart of an individual. The ring is flexible between an expanded configuration and a contracted configuration and is biased toward the contracted configuration. One or more anchors 920 protrude from the flexible ring for coupling the ring coaxially to the annulus such that the contracted configuration of the ring exerts an inward force to the annulus. Alternatively, or in addition, the two tongues can each have a length sufficient to prevent prolapse of a mitral valve when the ring is placed atop the leaflets of the mitral valve. In a further embodiment the tongue elements may be attached at a central point.

[0091] In yet another embodiment, a prosthetic for treating heart disease in general and a defective or diseased mitral valve in particular includes a wedge. The wedge has a length that is about equal to a length of the line of coaptation of a mitral valve. The wedge has a depth sufficient to prevent prolapse of a mitral valve when the wedge is placed atop an annulus of the mitral valve along the line of coaptation, and may provide a point of coaptation for each leaflet. One or more anchors protrude from the wedge for coupling the wedge to the annulus of the mitral valve. Methods of treatment using the wedge are also disclosed. The methods include inserting the wedge into an individual's heart, placing the wedge lengthwise along the line of coaptation of the mitral valve. The wedge is then secured to an annulus of

the mitral valve along the line of coaptation. The wedge may be positioned also just under one segment of the leaflet (likely P2 in the case of functional MR).

[0092] In yet another embodiment, a device for treating heart disease includes a clip for attachment to a free end of a heart valve leaflet. Figure 11A shows an exemplary embodiment of one or more clips 1101 that are positioned on free edges of the leaflets LF. Each of the clips 1101 has a shape that prevents flail of the leaflet by catching against an underside of an opposing leaflet. Methods of treatment using the clip are also disclosed. The methods include introducing the clip into an individual's heart and attaching the clip to a free end of a heart valve leaflet opposite the free end of an opposing leaflet of the heart valve so that the clip catches to the underside of the opposing leaflet during systole. In a further embodiment, a clip may be placed on both leaflets such that the clips meet or catch when the leaflets are in proximity. The clips may attach momentarily during systole, and then detach during diastole, or may clip permanently resulting in a double orifice mitral valve anatomy. The clips of this embodiment may include a magnetic element, or one may be magnetic and the other of a metal material attracted to said electromagnetic field of the magnetic clip.

[0093] In the case of magnetic clips, the clip elements may be placed on the underside of the leaflets (e.g. not necessarily on the free edge of the leaflet), provided that the magnetic field of the clip is sufficient to attract the opposing magnetic or metal clip element. This is further described with reference to Figure 11B, which shows pair of leaflets LF with a clip 1101 attached to the underside of each leaflet. At least one of the clips is magnetic, while the other clip is of an opposite magnetic polarity than the first clip or of a metal attracted to the magnetic field of the first clip. The magnetic field is sufficiently strong such that the clips 1101

can attach to one another either momentarily or permanently to coapt the leaflets, as shown in Figure 11C.

[0094] In another embodiment, shown in Figure 11D, a single clip 1101 is attached to one of the leaflets. The clip 1101 is sufficiently long to increase the likelihood that the clip 1101 will coapt with the opposite leaflet.

[0095] In yet another embodiment, a device for treating heart disease includes a wedge for placement under a heart valve leaflet. Figure 12 shows a schematic, cross-sectional view of the heart with a wedge 1205 positioned below at least one of the leaflets of the mitral valve. The wedge 1205 can be positioned below one or both of the leaflets. The wedge 1205 is sized to fit under the valve leaflet and caudal the annulus of the heart valve. The wedge 1205 can have a shape that is contoured so as to provide support to a lower surface of the leaflet. (In Figure 12, the left atrium is labeled LA and the left ventricle is labeled LV.) An anchor is attached to the wedge for coupling the wedge to a wall of the heart chamber adjacent the heart valve. The wedge forms a fixed backstop against the bottom side of the heart valve leaflet, thereby providing a location for the leaflet to coapt against, and/or providing support or "pushing up" a restricted leaflet.

[0096] Other embodiments are directed to altering the size, shape, chemistry, stiffness, or other physical attributes of heart valve leaflets. In one embodiment in particular, a method of treating heart disease includes obtaining access to a heart valve leaflet and injecting a stiffening agent into the leaflet to stiffen the leaflet and minimize flail.

[0097] Other embodiments are directed to the chordae that connect heart valve leaflets to the inner walls of the heart. In one embodiment in particular, a

method of treating heart disease includes obtaining access to a heart valve chord and cutting it mechanically or with energy such as a laser, or by heating the chordae to elongate them, thereby allowing the previously restricted leaflet to be less restricted so that it can coapt with the opposing leaflet.

[0098] In another embodiment directed to the chordae that connect heart valve leaflets to the inner walls of the heart, a cam-shaped ring is disclosed. The cam-shaped ring is sized to fit within a left ventricle of a heart. The ring forms a hole that is sized to receive two or more chordae tendineae. The ring is formed by connecting two detachable ends of the ring.

[0099] Methods of treatment using the cam-shaped ring are also disclosed. One method in particular includes introducing the ring into a left ventricle of a heart. One or more chordae tendineae are then surrounded by the ring, and the two ends of the ring are then attached to form a closed ring around the chordae tendineae. The ring is then rotated such that one or more of the chordae tendineae are shifted away from their initial orientation by the rotation of the cam-shaped ring. The ring may then be fixed in the rotated or tightened position.

[0100] An embodiment directed at the chordae of heart valve leaflets is now described. Figure 13A shows a device that can be used to alter a chordae. A method includes obtaining access to a chordae tendinea (chord) within an individual's heart chamber. The chordae is then cut at a point along its length so that a length of the chorda tendinea is freed from the heart chamber leaving behind a length of chorda tendinea having a free end and an end attached to an edge of a heart valve.

[0101] With reference to Figure 13A, a synthetic chord 1005 of greater length than the free length of chordae is introduced into the heart chamber. One end of the synthetic chordae 1005 is connected to a wall 1305 of the heart chamber or to a muscle attached to the wall of the heart chamber. Another end of the synthetic chord is attached to the free end of the chorda tendinea or to the leaflet.

[0102] In this regard, the end of the chord 1005 that is attached the wall 1305 can have any of a variety of devices that facilitate such attachment. Figures 13B and 13C show enlarged views of attachment devices contained within box 13 of Figure 13A. The attachment devices can be used to attach the chord 1005 to the wall1305. In Figure 13B, the attachment device 1310 is an enlarged ball having a distal trocar for penetrating the wall 1305. In Figure 13C, the attachment device 1310 is a hook that is configured to penetrate through the wall 1305. It should be appreciated that the attachment device 1310 can have other structures and it not limited to the structures shown in Figures 13B and 13C. In variations of these embodiments, it may be advantageous to adjust the length of the chordae (synthetic, or modified), determine the therapeutic effect of the shortening or lengthening, and then fix the chordae at the most efficacious location.

[0103] Other embodiments are directed to atrial or ventricular remodeling to alter the shape of an atrium or ventricle. Figure 14 shows a cross-sectional view of the heart with a first and second anchor attached to a wall of the heart. The system includes a first anchor 1410a having a screw portion 1415 for screwing into a wall of the heart and a connector portion. The connector portion is rotatable around an axis of rotation. The first anchor includes a power source to power rotation of the connector portion and a receiver for receiving telemetric signals from an external controller for controlling the rotation of the connector portion. The system includes a

second anchor 1410b having a screw portion 1415b for screwing into a wall of the heart and a connector portion. Also included is a tether 1420 having two free ends. One of the free ends is coupled to the connector portion of the first anchor, and the other free end is coupled to the connector portion of the second anchor. An external controller is also included. The external controller has a telemetric transmitter for communicating with the receiver and controls the rotation of the connector portion. Alternatively, the anchors may be placed with a torqueable catheter.

[0104] In another embodiment, a method of altering a geometry of a heart includes introducing a first coupler into a heart chamber. The first coupler has an anchor portion and a connector portion. The connector portion is rotatable around an axis of rotation and is connected to a power source to power rotation of the connector portion. The power source is in communication with a telemetric signal receiver. The first coupler is secured to the wall of the heart chamber by anchoring the anchor portion to the wall. A second coupler is introduced into the heart chamber. The second coupler includes an anchor portion and a connector portion. The second coupler is secured to the wall of the heart chamber by anchoring the anchor portion to the wall at a distance from the first coupler.

[0105] A tensile member is introduced into the heart chamber. One end of the tensile member is connected to the connector portion of the first coupler, and another end of the tensile member is connected to the connector portion of the second coupler. The distance between the first and second couplers is adjusted by transmitting a telemetric signal to the receiver, thus causing the connector portion to rotate around the axis of rotation and threading the tensile member around the connector portion to reduce the distance between the first and second couplers.

[0106] In another embodiment, a system for altering the geometry of a heart chamber includes a planar tensile member having substantially inelastic material. At least two anchors are included for anchoring the planar tensile member to an inner wall of a heart chamber. The planar tensile member is substantially shorter in length than a left ventricle of a heart so that when the planar tensile member is anchored in a caudal direction along a length of the left ventricle a tensile force exerted by the planar tensile member between the two anchors prevents the left ventricle from dilating caudally.

[0107] In another embodiment, a method for altering the geometry of a heart includes providing a tensile member having a substantially inelastic material. The tensile member is substantially shorter in length than a left ventricle of a heart. The tensile member is inserted into the left ventricle of the heart and a proximal end of the tensile member is anchored to the left ventricle adjacent the mitral valve. A distal end of the tensile member is anchored to the left ventricle caudal the proximal end so that a tensile force exerted by the tensile member between the two anchors prevents the left ventricle from dilating caudally.

[0108] Other embodiments are directed to strengthening or reshaping the left ventricle of the heart. In one embodiment in particular, a method of reinforcing the left ventricle includes injecting a strengthening agent into a wall of the left ventricle in an enlarged region of the ventricle, as shown in Figure 15. Figure 15 shows a catheter 1510 that has been introduced into the heart. The catheter 1510 has an internal lumen through which the strengthening agent 1512 can be injected. A proximal end of the catheter is connected to a source of the strengthening agent and a distal end of the catheter is configured to release the strengthening agent. As

shown in Figure 15, the distal end of the catheter is positioned at or near a wall of the heart and the strengthening agent 1512 is injected into the wall of the heart.

[0109] In another embodiment, a method is directed to altering the geometry of a heart. The method includes injecting a polymerizing agent into a pericardial space adjacent a left ventricle, thereby exerting a medial (inward) force against the left ventricle.

[0110] In yet another embodiment, a method of altering the geometry of a heart includes inserting a balloon into a pericardial space adjacent to a left ventricle of the heart, or extend into the pericardium of the heart. The balloon is inflated by injecting it with a fluid, and it exerts a medial force against the left ventricle upon inflation. In certain embodiments, the balloon can be inflated at the time of implantation, or at a later time. If inflated at a later time, the balloon would be self-sealing, and may be inflated by accessing the balloon with a needle placed through the chest wall.

[0111] Other embodiments are directed to adjusting the length or orientation of papillary muscles. Figure 16 shows a schematic view of the heart showing the papillary muscles PM. With reference to Figure 16, a method of treating heart disease includes inserting an anchor, cuff or sleeve 1205 into the left ventricle of an individual's heart, and sliding a cuff or sleeve around a papillary muscle P. The size of the cuff or sleeve is reduced so that the cuff or sleeve squeezes the papillary muscle. As the size of the cuff or sleeve is reduced, the papillary muscle stretches and increased in length.

[0112] In yet another embodiment, a method of treating heart disease includes obtaining access to a papillary muscle in a left ventricle of the heart. The

papillary muscle is cut and reattached at a new location on an inner wall of the ventricle closer to the mitral valve.

[0113] Additional embodiments that employ magnets in the heart are now described with reference to Figures 17-19, which show cross-sectional views of the heart. With reference to Figure 17, in one embodiment one or more magnets 1705 are implanted or otherwise attached to a wall 1710 of the left ventricle LV. One or more other magnets 1715 are implanted or otherwise attached to a wall 1720 of the right ventricle. The magnets 1705 and 1715 are attached to the walls 1710 and 1720 such that they assert an attractive magnetic force (as represented by the arrows 1725 in Figure 17) toward each other. The magnetic force 1725 assists in remodeling of the left ventricle during pumping of the heart. That is, the magnets 1705 and 1715 are urged toward one another (thereby also urging the walls 1710 and 1720 toward one another) to re-shape either the annulus AN or the left ventricle LV. The annulus or the left ventricle LV are re-shaped in a manner that reduces or eliminates backflow through the mitral valve MV. It should be appreciated that a similar procedure can be performed on the right ventricle RV and associated valves.

[0114] Figure 18A shows another embodiment of a procedure wherein magnets are implanted in the heart to geometrically reshape the annulus or the left ventricle. One or more magnets 1705 are implanted or otherwise attached to a first wall 1710a of the left ventricle LV. One or more magnets 1705 are also implanted or otherwise attached to a second, opposed wall 1710b of the left ventricle. The magnets on the opposed walls 1710a, 1710b exert an attractive magnetic force toward one another to draw the walls 1710a, 1710b toward one another and re-shape the left ventricle LV or the annulus AN.

[0115] Another embodiment of a procedure uses magnets to anchor tethers within the heart at various locations to optimize the shape of cardiac structures to improve cardiac function. The tethers are placed to either reshape the cardiac structure or to prevent dilatation of the structure over time. The tethers must be securely anchored to the heart structures. A method of anchoring which enables tethering in various positions and directions within the cardiac structures is important for the clinician to optimize cardiac reshaping based on each individual patient anatomy and disease state. A method of anchoring which is atraumatic is also desirable.

[0116] Figure 18B shows a side view of the heart with sets of magnets A, A1, B, and B1 positioned to various locations of the heart or to anatomical structures adjacent the heart. In one embodiment, at least one magnet A is placed on the interventricular septum within the right ventricle RV. At least one magnet A1 is placed within the left ventricle LV opposite magnet A. The magnetic force between A and A1 maintains the position of the magnets. The magnets may be enclosed in materials that will promote tissue in-growth and healing to the interventricular septum to ensure stability of location and to eliminate the need for long term anti-coagulation. Additionally, the enclosure material which is flexible and can be delivered in a low profile can be significantly larger in size than the magnets to increase the surface area of contact with the heart wall which will increase the tension that can ultimately be placed on the anchor over time.

[0117] A second set of magnets B and B1 are then delivered to another location selected within or adjacent to the heart. The set of magnets A/A1 are attached to the set of magnets B/B1 using at least one tether 1805, as shown in Figure 18B. The tether 1805 can be attached to either or both of the magnets A/A1

at one end and to either of both of the magnets B/B1 at an opposite end. When the set of magnets B/B1 are tethered under tension to the set of magnets A/A1, a change in the shape of the cardiac structure results to improve cardiac function. Figure 18B shows magnet B positioned in the LV and B1 positioned in a blood vessel BV adjacent to the heart. The magnetic force between B and B1 maintains the location of B and B1. Magnets B and B1 are delivered on or within materials and structures which promote healing and increase the amount of tension that can be placed on the anchor over time. For example, magnet B1 can be delivered on a stent which is of a length, diameter and material which will heal within the BV to provide sufficient resistance to forces placed on it by the tethers.

[0118] The tethers may be pre-attached to the magnets A and B1 or they may be attached after A and B1 have been positioned. The tether length may be shortened and/or adjusted after placement of the anchors. Alternatively the final tether length may be pre-selected based on the patient's cardiac structure geometry and the effect the clinician desires. Placing sets of magnets in this method, enables anchoring of tethers within the heart in various positions and angles which provides increased flexibility and variation for clinicians to select optimal re-shaping of the cardiac structures based on specific patient characteristics.

[0119] Examples which demonstrate the flexibility of this approach include placing anchors at the annulus and at the apex of the heart and tethered to shorten the length of the LV; anchors can be placed in the around the annulus and tethered to change the shape of the annulus. More specifically, one or more sets of magnets can be placed in the RA and LA at the level of the mitral valve annulus (on the anterior side of the annulus) and one or more sets of magnets can be placed in the LA and LV on opposite sides of the annulus on the posterior portion of the annulus.

The posterior sets of magnets can then be tethered to the anterior sets of magnets to change the shape of the annulus. Alternatively, the magnet anchors can be placed at the level of the annulus in the LA and in a BV adjacent to the heart at the level of the annulus and these then tethered to the anterior annulus magnet anchor described above.

[0120] The magnets A and A1 can also be a single magnet that extends through the interventricular septum. Moreover, only one of the magnets A or A1 need be implanted. One or more magnets B and/or B2 are located opposite the location of the magnet(s) A and/or A1. The magnet(s) B is located within the left ventricle opposite the magnets A/A1, such as on the left ventricular wall. The magnet B1 is located on an anatomical structure adjacent the heart, such as on a blood vessel BV.

[0121] In another embodiment shown in Figure 18C, the magnets A, A1, B, and B1, or combinations thereof, are implanted in the heart without tethers. The magnets A, A1, B, and B1 can be positioned in various combinations so as to exert magnetic attractions to one another to re-shape the left ventricle or the mitral valve annulus. For example, the magnets A and B can be implanted such that they exert an attractive magnetic force relative to one another. The magnets A and B2 can alternately be implanted. Other possible combinations are the magnets A1 and B or the magnets A1 and B2. The magnets can be implanted without tethers such that an attractive magnetic force F causes the magnets and the attached region of the heart to move toward one another to re-shape the heart. Alternately, the magnets can be attached to one another with tethers.

[0122] In yet another embodiment, one or more magnets 1705 are implanted in the walls 1710 of the left ventricle LV and/or the right ventricle RV, as shown in Figure 19. The magnets 1705 are positioned in opposed locations on the walls 1710 and one or more tethers 1905 attach opposed pairs of magnets 1705 to one another. One or more of the tethers 1905 extend through the interventricular septum to connect a first magnet disposed in the left ventricle and a second magnet disposed in the right ventricle. In certain embodiments, magnet elements do not include tethers, but rely on the magnetic attraction to each other to remodel the tissue between them. For example, a magnetic element may be placed on either side of the interventricular septum, or one element within the septum. Another magnetic element may be placed on or within the opposite left ventricular wall, or in an adjacent vessel on the left ventricular wall. The electromagnetic field of such elements can then interact to cause a remodeling of the left ventricle to assist with ventricular function.

[0123] The tethers 1905 can be elastic so to exert an attractive force between the attached magnets 1705 and re-shape the left ventricle LV or annulus AN. Alternately, or in combination with elastic tethers, the tethers 1905 can be shortened in length after placement to thereby pull the walls of the left ventricle LV toward one another and re-shape the left ventricle LV or the annulus AN. In combination with the force provided by the tethers 1905, the magnets 1705 exert an attractive magnetic force toward one another to assist in pulling the heart walls toward each other.

[0124] It should be appreciated that one or more magnets can be positioned in other locations of the heart or adjacent anatomical structures for re-shaping of the heart. For example, one or more magnets can be positioned around

the annulus AN or can be positioned in the coronary sinus in such a manner that the magnets exert attractive forces toward one another to cause re-shaping of a desired portion of the heart.

[0125] In another embodiment, cardiac re-shaping is achieved through percutaneous placement of one or more tethers that are cinched or anchored in the walls of the left ventricle LV. The tethers provide tension between the walls of the left ventricle to reshape the left ventricle LV in a desired manner. Figure 20 shows a cross-sectional view of the left ventricle LV with a tether 2010 positioned therein. The tether 2010 has a first end anchored to a first wall of the left ventricle LV and a second end anchored to an opposed wall of the left ventricle LV. The tether 2010 is tensioned to pull the walls toward one another (as represented by the phantom lines 2012 in Figure 20) and re-shape the left ventricle LV. It should be appreciated that the phantom lines 2012 in Figure 20 are merely representative of the geometric re-shaping. The left ventricle LV can be re-shaped in various manners and the amount of re-shaping can vary depending on the tension applied to the tether 2010 and the location of attachment to the walls of the left ventricle LV. The tether may be inelastic or somewhat elastic.

[0126] The tether 2010 can be anchored or otherwise attached to the walls in various manners. In an exemplary embodiment, a patch 2015 (shown in Figure 20) of material is positioned on an exterior surface of the ventricular wall and is attached to one end of the tether 2010. A similar patch can also be positioned on the opposed wall and attached to the opposite end of the tether.

[0127] With reference to Figure 21, the patch is delivered to a desired location using a catheter 2105 having a sharpened distal end 2110 that is positioned

within the left ventricle LV. The catheter 2105 can be delivered to the left ventricle LV in various manners, including trans-aortically (via the aorta), trans-septally (by piercing the interventricular septum), and trans-atrially (via the left atrium) pursuant to well-known methods. As shown in Figure 22, the sharpened distal end 2110 pierces the ventricular wall such that the distal end 2110 is positioned exterior to the ventricular wall. The catheter 2105 has an internal delivery lumen having an opening at the distal end 2110. The patch 2015 is configured to be transported in a contracted state through the delivery lumen and delivered out of the opening at the distal end 2110, where the patch 2015 expands into an expanded state at the exterior of the ventricular wall to seal against the exterior of the left ventricular wall.

[0128] When positioned at the exterior of the ventricular wall, the patch 2015 is configured to act as a reservoir that receives a fluid material that can be delivered to the patch via the delivery lumen of the catheter 2105. The fluid material has a first viscous state of sufficient fluidity such that the material can flow through the delivery lumen of the catheter 2105 and out of the distal end 2110 to the location of the patch 2015. The fluid material changes to a second viscous state when positioned exterior to the ventricular wall at the patch 2015. The second viscous state is of greater viscosity (i.e., more resistant to flow) than the first viscous state such that the fluid material provides support and a level of rigidity to the patch 2015 and to the left ventricular wall. The fluid material can change to the second viscous state after a predetermined time period, after contact with the patch, or when the patch is completely filled. A catalyst can be injected into the fluid material to cause it to change to the second viscous state.

[0129] As shown in Figure 23, the catheter 2105 can then be disengaged from the patch 2015 such that the patch 2015 is disposed exterior to the ventricular

wall. The patch 2015 can be firmly attached to the ventricular wall (such as using an adhesive) to minimize wear or friction between the patch and the ventricular wall. Next, an end of the tether 2010 is attached to the patch 2015. The catheter 2105 can be used to deliver the tether 2010 to the patch 2015 or, alternately, a second catheter can be used. In one embodiment, the tether 2015 is already positioned in a delivery lumen of the catheter 2010 while the patch 2015 is being delivered. The catheter 2010 is then pulled back while the end of the tether 2015 remains attached to the patch 2015 to thereby let the tether 2010 out from the catheter 2010, as shown in Figure 23.

[0130] With reference now to Figure 24, a second patch 2415 is deployed in or exterior to an opposed ventricular wall in a manner similar to that described above. The opposite end of the tether 2010 is then attached to the second anchor 2415 such that the tether 2010 extends between the two anchors, as shown in Figure 20. Alternately, as shown in Figure 24, a second tether 2420 is attached at a first end to the second anchor 2415. As shown in Figure 25, the two tethers 2010 and 2420 can then be attached together at opposite ends from the patches, such as by using a clip 2510, to form a single attachment tether between the patches 2015 and 2415. The tether 2510 can be twisted or adjusted within the clip to tension the resulting attachment tether between the patches 2415 and 2015 and pull the ventricular walls toward one another via the tether. Once properly tensioned, the tether can be clipped or clamped to maintain its position.

[0131] In another embodiment, shown in Figure 26, a needle 2610 or delivery catheter is passed trans-thoracically into the left ventricle LV to deliver a patch 2615 to the exterior of the ventricular wall, as described above. A sealing means, such as a sealing balloon, can be used to seal one or more puncture holes in

the wall of the left ventricle caused by the needle 26 during delivery of the patch 2615. Visualization means, such as fluoroscopy, can be used to visualize proper placement of the needle 2610. A second patch is attached to an opposed wall to form a tether attachment between the walls, as shown in Figure 20. The tether is then tensioned to pull the walls together and re-shape the left ventricle or annulus of the mitral valve in a desired manner.

[0132] In other embodiments, described with reference to Figures 27-31, cardiac re-shaping is achieved by manipulation of the papillary muscles. Figure 27 shows a schematic, cross-sectional view of the left ventricle LV in a healthy state with the mitral valve closed. The valve chordae CH connect the leaflets LF of the mitral valve to the papillary muscles PM. The papillary muscles PM and the and chordae CH are positioned such that at least a portion of the leaflets LF contact one another when the mitral valve is in the closed state, resulting in functional coaptation of the leaflets.

[0133] Figure 28 shows the left ventricle LV in a dysfunctional state. The valve chordae CH or the papillary muscles PM are damaged or otherwise dysfunctional such that the leaflets LF do not properly coapt (contact one another). The dysfunction can be manifested by excess tension in the chordae CH such that a gap is located between the leaflets LF, or in some cases one leaflet may function at a different level from the other (e.g. lower (prolapse) or higher (flail)) thereby limiting the ability of the mitral valve to close resulting in mitral regurgitation. The dysfunctional left ventricle LV and in some cases leaflet prolapse or flail, can be treated by manipulating papillary muscles PM to adjust the position of the leaflets LF. In one embodiment, the papillary muscles PM are repositioned toward one another to reduce the distance between the papillary muscles PM.

[0134] In an embodiment described with reference to Figure 29, a biasing member, such as a rod of adjustable length, or a spring 2910, is mounted between the papillary muscles PM with a first end of the spring 2910 attached to a first papillary muscle and a second end of the spring 2910 attached to a second papillary muscle. The spring 2910 has a pre-load such that the spring 2910 provides a biasing force (represented by the arrows 2915 in Figure 29) that pulls the papillary muscles PM toward one another. Such a spring may be covered with polyester fabric or other coating to promote ingrowth into the muscle tissue and minimize the potential for clot formation. The repositioning of the papillary muscles PM re-shapes the left ventricle and/or changes the distance that the leaflets need to move on the chordae CH such that the leaflets LF contact one another to close the mitral valve. The tension provided by the spring 2910 can be varied or different springs can be used to achieve a proper repositioning of the papillary muscles PM. The tension may be modified at the time of the procedure or during a subsequent procedure if it is determined that additional coaptation is required.

[0135] In another embodiment, described with reference to Figure 30, a suture 3010 is mounted between the papillary muscles PM with a first end of the suture 3010 attached to a first papillary muscle and a second end of the suture 3010 attached to a second papillary muscle. The suture 3010 can be attached to the papillary muscles in various manners. For example, an attachment device 3015, such as an anchor, cuff or sleeve, can be positioned around or partially around each of the papillary muscles. The ends of the suture 3010 are attached to the attachment devices 3015 to secure the suture 3010 to the suture to the papillary muscles.

[0136] The suture 3010 is tensioned such that it provides a force that pulls the papillary muscles PM toward one another. The suture 3010 can be tensioned, for example, by twisting the suture 3010 to reduce its the overall length and thereby reduce the distance between the papillary muscles PM, and fixing the suture with a crimping element or other stay element. The amount of twisting or shortening can be varied to vary the tension provided by the suture 3010. In addition, a crimping member may be used to fix the sutures once a desired tension between the muscles is reached. Exemplary crimping members are described in International Patent Application Number PCT/US03/06149, which is incorporated herein by reference in its entirety. As in the previous embodiment, the repositioning of the papillary muscles PM re-shapes the left ventricle and/or changes the tension on the chordae CH such that the leaflets LF contact one another to close the mitral valve. Cuffs or sleeves may be placed around the papillary muscles PM to such as those previously described, to affect the repositioning.

[0137] With reference now to Figure 31, the papillary muscles PM can also be repositioned by snaring the papillary muscles. A snare 3110 comprised of a looped strand of material is positioned around the chordae CH at or near the location where the chordae attach with the papillary muscles PM. The snare 3110 is tightened to draw the papillary muscles PM toward one another and re-shape the left ventricle and/or changes the distance that the leaflets need to travel during systole such that the leaflets LF contact one another to close the mitral valve.

[0138] In yet another embodiment, shown in Figure 36, one or more clips 3610 are clipped to each of the papillary muscles PM. The structure of the clips 3610 can vary. A tether 3615 attaches the clips 3610 to one another. The tether 3615 is cinched to shorten the length of the tether 3615 and pull the papillary

muscles PM toward one another and re-shape the left ventricle and/or changes the distance that the leaflets need to travel during systole such that the leaflets LF contact one another to close the mitral valve.

[0139] In yet another embodiment, shown in Figure 37, one or more clips 3610 are clipped to opposed walls of the left ventricle LV. The clips 3610 can be delivered to the left ventricle using a delivery catheter 2105. A tether attaches the clips to one another. The tether is cinched to shorten the length of the tether and pull the ventricular walls toward one another and re-shape the left ventricle and/or changes the distance that the leaflets need to travel during systole such that the leaflets LF contact one another to close the mitral valve.

[0140] In all embodiments, once the papillary muscles are fixed or repositioned, it may be advantageous to further treat the area by selectively elongating or shortening the chordae tendinae to achieve further optimal valve function. In addition, a mitral valve clip may be deployed to augment the desired valve function, either before papillary or chordal manipulation, or after, if the desired leaflet coaptation is not achieved with one particular approach.

[0141] As discussed above with reference to Figure 28, a dysfunctional left ventricle can be manifested by excess tension in the chordae CH such that a gap is positioned between the valve leaflets LF. It can be desirable to eliminate or relieve the excess tension by cutting the chordae CH, and/or cutting the chordae and replacing them with artificial chordae. Prior to cutting the chordae, it can be desirable to evaluate the placement of the artificial chordae to confirm that implantation of the chordae will indeed provide the desired clinical result. This process is now described with reference to Figures 32-35.

[0142] Figure 32 shows a leaflet grasping device 1100 that is configured to grasp and secure the leaflets of the mitral valve. The device 1100 and corresponding methods of use are described in more detail in U.S. Patent Application Serial No. 10/635,776, entitled "Methods and Apparatus For Cardiac Valve Repair", which is incorporated herein by reference in its entirety. Additional leaflet grasping devices are described in U.S. Patent Application Serial No. 10/441,508, filed May 19, 2003, U.S. Patent No. 6,269,819, issued August 7, 2001, and U.S. Patent No. 6,461,366, issued October 8, 2002, all of which are expressly incorporated by reference herein.

[0143] Referring to Figure 32, the device 1100 is comprised of a catheter shaft 1102 having a distal end 1104 and a proximal end 1106. The catheter shaft 1102 is comprised of, among others, a conduit 1108, a coaxial outer sheath 1110, a central lumen 1111 through which a double-jaw grasper 1113 may be inserted, and a central guidewire lumen 1105. The catheter shaft 1102 can have additional lumens for the passage of one or more needles, as described more fully below.

[0144] Toward the distal end 1104, an optional pair of stabilizers 1112 are fixedly mounted on the outer sheath 1110 at their proximal end 1114 and fixedly attached to extenders 1116 at their distal end 1118. The stabilizers 1112 are shown in an outwardly bowed position, however they may be inwardly collapsed by either extending the extenders 1116 or retracting the outer sheath 1110. Bowing may be achieved by the reverse process.

[0145] The double-jaw grasper 1113 is comprised of two articulating jaw arms 1120 which may be opened and closed against the central shaft 1122 (movement depicted by arrows) either independently or in tandem. The grasper

1113 is shown in the open position in Figure 32. The surfaces of the jaw arms 1120 and central shaft 1122 may be toothed, as shown, or may have differing surface textures for varying degrees of friction. The jaw arms 1120 each include a needle passageway 1121 comprised of a cutout or a slot that extends at least partially along the length of each jaw arm 1120. As described in more detail below, the needle passageway provides a location where a needle can pass through the jaw arm 1120 during manipulation of the papillary muscle.

[0146] The above described components may be manipulated and controlled by a handle 1126 connected to the proximal end 1106 of the catheter shaft 1102, as shown in fig. 86. the handle 1026 permits independent control of the components described above.

[0147] Referring to Figures 33A-C, the device 1100 may be used at least temporarily grasp and restrain the valve leaflets LF of the mitral valve MV. The double-jaw grasper 1113 extends through the valve such that the leaflets L1, L2 are grasped from below. Thus, the device 1100 is termed "atrial-ventricular."

[0148] Referring to Figure 33A, the atrial device 1100 may be stabilized against the mitral valve MV. The stabilizers 1112 may be positioned on the superior surface of the valve leaflets LF1, LF2 at a 90 degree angle to the line of coaptation. The grasper 1113 may be advanced in its closed position from the conduit 1108 between the leaflets LF1, LF2 until the jaw arms 1120 are fully below the leaflets in the ventricle. At this point, the grasper 1113 may be opened and retracted so that the jaw arms 1120 engage the inferior surface of the leaflets LF1, LF2. In this manner, the leaflets are secured between the stabilizers 1112 and the jaw arms 1120.

[0149] Referring to Figure 33B, the grasper 1113 will gradually close, drawing the leaflets LF1, LF2 together while maintaining a secure hold on the leaflets between the jaw arms 1120 and the stabilizers 1112. This may be accomplished by number of methods. For example, the stabilizers 1112 may be gradually collapsed by either extending the extenders 1116 or retracting the outer sheath 1110. As the stabilizers 1112 collapse, the jaw arms 1120 may collapse due to spring loading to gradually close the grasper 1113. Alternatively, the jaw arms 1120 may be actuated to close against the central shaft 1122 applying force to the stabilizers 1112 causing them to collapse. In either case, such action allows the stabilizers 1112 to simultaneously vertically retract and withdraw from the leaflets as the leaflets are clamped between the jaw arms 1120 and the central shaft 1122. In this manner, the leaflets are effectively "transferred" to the grasper 1113. Referring to Figure 33C, once the collapsed stabilizers 1112 are completely withdrawn, the leaflets LF1, LF2 are held in vertical opposition by the grasper 1113 in a more natural coaptation geometry.

[0150] With reference now to Figure 34, a needle 3410 is advanced from the left atrium into the left ventricle. The needle 3410 can be passed through a lumen in the device 1100 or it can be passed external to the device 1100. In any event, the needle 3410 passes through a leaflet LF and into a papillary muscle PM. As mentioned, the jaw arms 1120 have needle passageways 1121 (shown in Figure 32) that permit passage of the needle through the jaw arms 1120.

[0151] The needle 3410 is attached to a suture 3415 that extends distally through the device 1100. The suture 3415 is then anchored to the papillary muscle PM such that the suture 3415 provides an attachment for holding, pulling, or otherwise manipulating the papillary muscle PM. The tension in the suture 3415 can

be adjusted to re-position the papillary muscle PM such that the leaflets LF contact one another to close the mitral valve. The same process can be performed with the other papillary muscle.

[0152] With the sutures 3415 holding the papillary muscles PM in a desired position, as shown in Figure 35, the chordae CH may be cut. The sutures 3415 function as artificial chordae that retain the leaflets LF and papillary muscles PM in a desired orientation.

[0153] A fixation device such as a clip can then be attached to the leaflets using methods and device described in U.S. Patent Application Serial No. 10/635,776, filed August 5, 2003, U.S. Patent Application Serial No. 10/441,508, filed May 19, 2003, U.S. Patent No. 6,269,819, issued August 7, 2001, and U.S. Patent No. 6,461,366, issued October 8, 2002, all of which are expressly incorporated by reference herein. The sutures 3415 can be attached to the clip 3510 or directly to the leaflets LF. It should be appreciated that any quantity of sutures 3415 can be used as artificial chordae between the leaflets and the papillary muscles. It should be appreciated that the leaflet clips can also be used in conjunction with cutting, elongating, or shortening of the chordae pursuant to the methods described above.

[0154] Prior to permanently placing the chordae or clips, the result can be previewed on ultrasound (TEE, ICE, echocardiography), to determine if the appropriate valve coaptation is restored. In addition, it is within the scope of the present invention to implant a mitral valve clip in addition to performed papillary muscle approximation or chordal implantation.

[0155] Although embodiments of various methods and devices are described herein in detail with reference to certain versions, it should be appreciated

that other versions, embodiments, methods of use, and combinations thereof are also possible. Therefore the spirit and scope of the appended claims should not be limited to the description of the embodiments contained herein.

CLAIMS

1. A method of treating a heart, comprising:

attaching a first device to a first location of a wall of a left ventricle of the heart;

attaching a second device to a second location of the heart, wherein the second location is located opposite the first location; and

moving the first device and the second device toward one another to cause the first location and second location to move toward one another so as to re-shape at least one of the mitral valve annulus or the left ventricle in a manner that reduces backflow through the mitral valve.

2. The method of claim 1, wherein the second location is on a wall of a right ventricle of the heart.

3. The method of claim 1, wherein the second location is on a wall of the left ventricle of the heart.

4. The method of claim 1, wherein the second location is on an interventricular septum of the heart.

5. The method of claim 1, wherein at least one of the first and second devices comprises a magnet, and wherein a magnetic force causes the first and second devices to move toward one another.

6. The method of claim 1, wherein the first and second devices are interconnected by a tether.

7. The method of claim 6, wherein the tether is elastic such that the tether exerts an attractive force between the first and second device to cause the first and second device to move toward one another.

8. The method of claim 6, further comprising shortening the length of the tether so as to move the first device and second device toward one another.

9. The method of claim 6, wherein the first and second devices comprise magnets.

10. The method of claim 6, wherein the tether extends through a interventricular septum of the heart.

11. A method of treating a heart, comprising:

coupling at least one valve to a steerable delivery device;

percutaneously introducing the valve into the heart using the steerable delivery device; and

placing the valve in a pulmonary vein of the heart, wherein the valve regulates blood flow into the left ventricle of the heart.

12. The method of claim 11, wherein placing at least one valve in a pulmonary vein of the heart comprises placing a valve in each of the four pulmonary veins of the heart.

13. The method of claim 11, wherein the at least one valve is placed near an ostium of the pulmonary vein.

14. A method of treating a heart, comprising:

coupling a first wedge-shaped device to a steerable delivery device, wherein the first device has a contact surface adapted to be positioned adjacent a first mitral valve leaflet of the heart;

percutaneously introducing the first device into the heart using the steerable delivery device; and

securing the first device to the heart such that the first mitral valve leaflet is positioned adjacent the contact surface of the device.

15. The method of claim 14, wherein the first device is secured below the first leaflet such that the contact surface supports a lower surface of the leaflet.

16. The method of claim 14, wherein the first device is secured above the first leaflet such that the contact surface supports an upper surface of the leaflet.

17. The method of claim 14, further comprising:

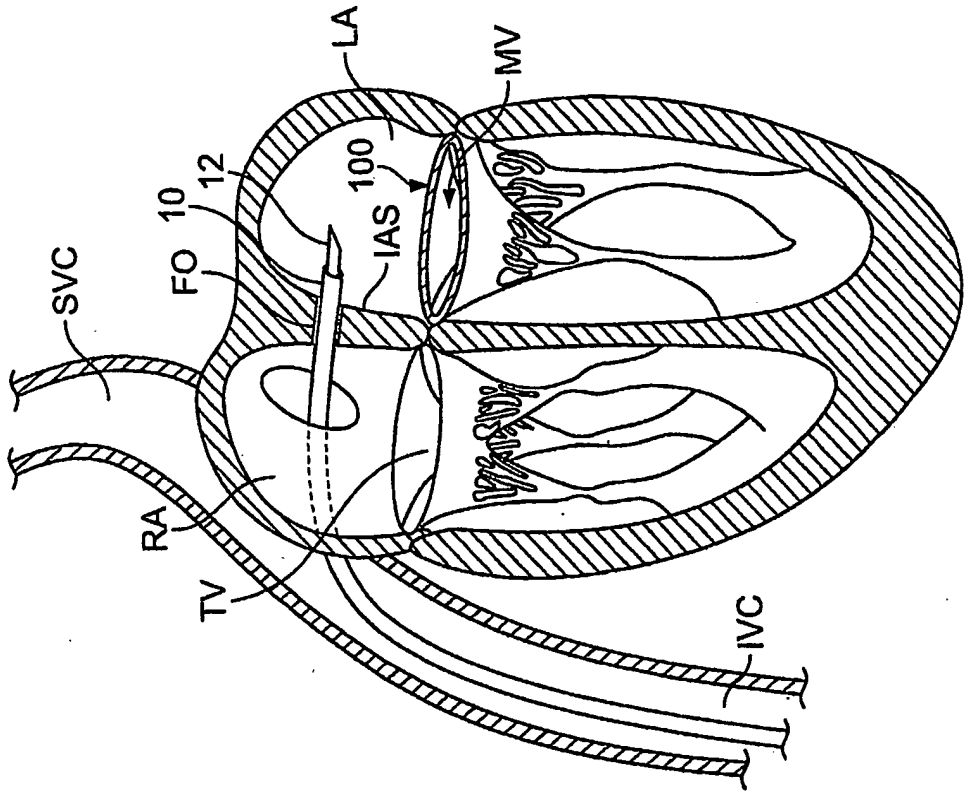
introducing a second wedge-shaped device into the heart, wherein the second device has a contact surface adapted to be positioned adjacent a second mitral valve leaflet;

securing the first device to the heart such that the second mitral valve leaflet is positioned adjacent the contact surface of the device.

18. A device for treating heart disease comprising a prosthetic comprising:

a wedge having a length that is about equal to a length of a line of coaptation of a mitral valve and a depth sufficient to prevent prolapse of a mitral valve when the wedge is placed atop an annulus of the mitral valve along the line of coaptation; and

one or more anchors protruding from the wedge for coupling the wedge to the annulus of the mitral valve.


LA
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12
10
IAS
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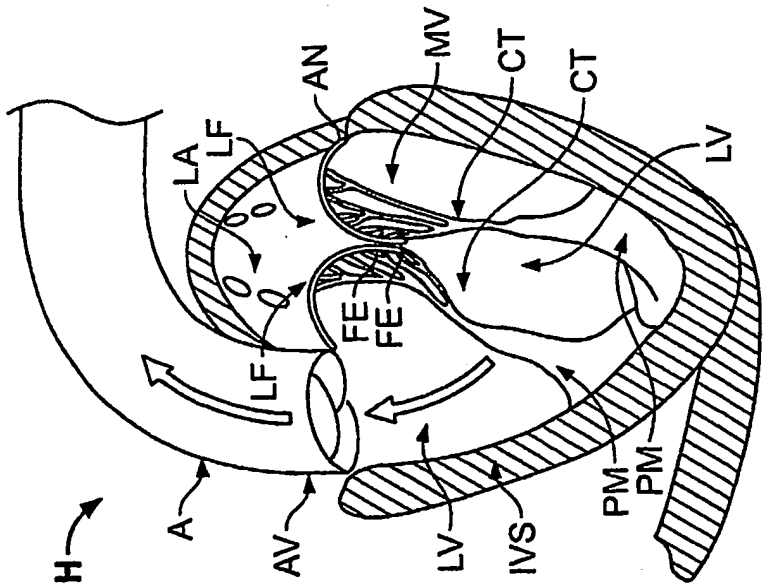
SVC
RA
TV
IVC

FIG. 1B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CT
CT
LV
LA
LF
FE
FE
LF
H
A
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LV
IVS
PM
PM

FIG. 1A

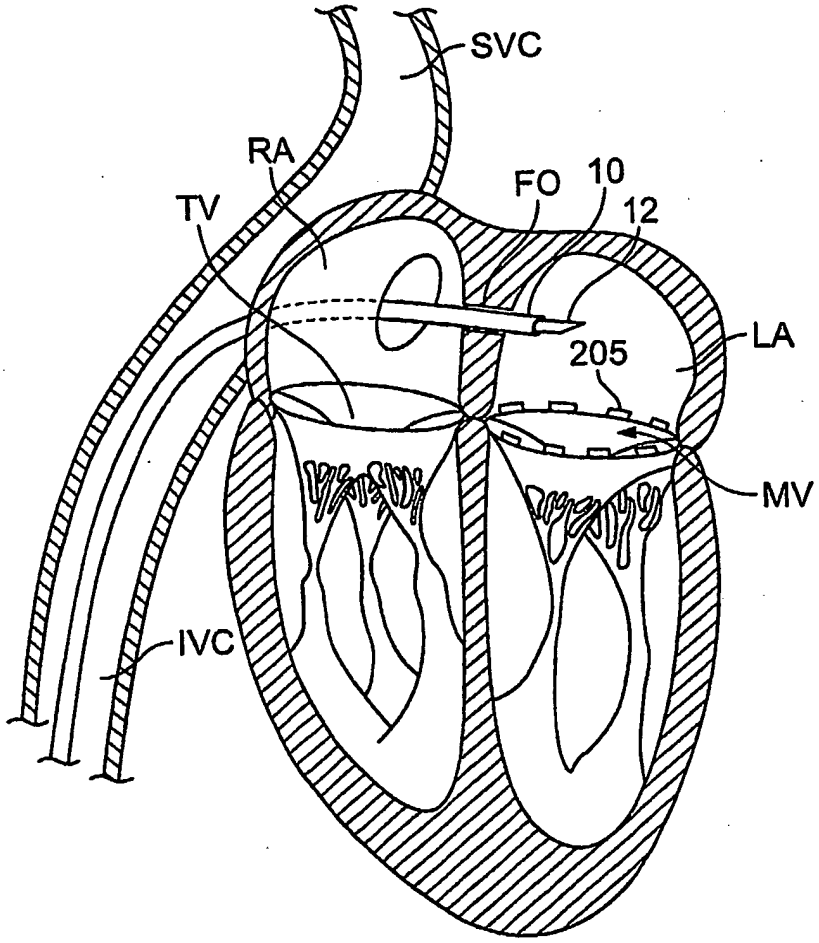


FIG. 2A

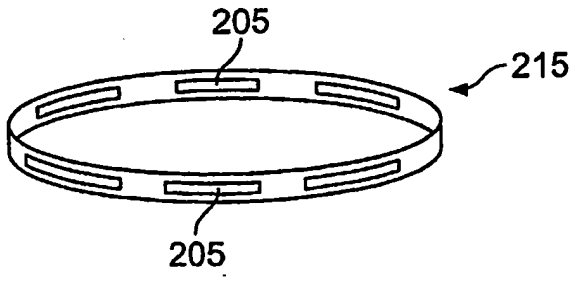
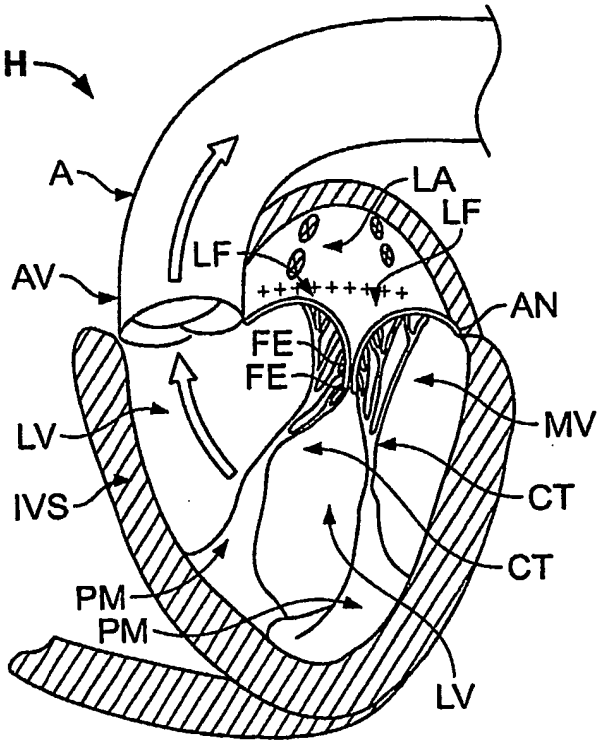


FIG. 2B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LV
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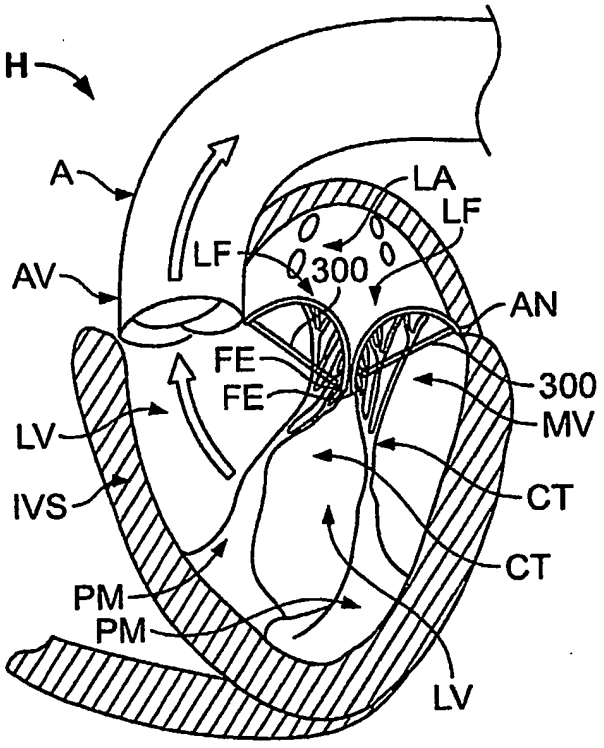
CT
PM
PM
LV

FIG. 3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AV
AN
FE
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300
MV
LV
CT
IVS
CT
PM
PM
LV

FIG. 4

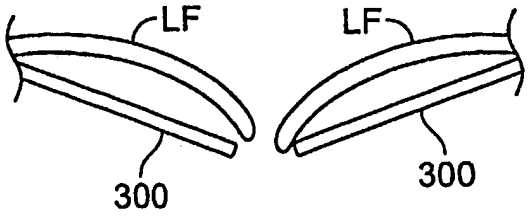

FIG. 5A

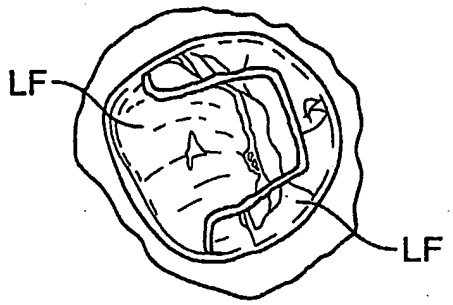

FIG. 5B

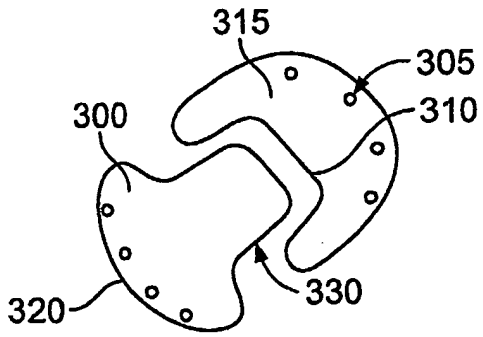

FIG. 5C

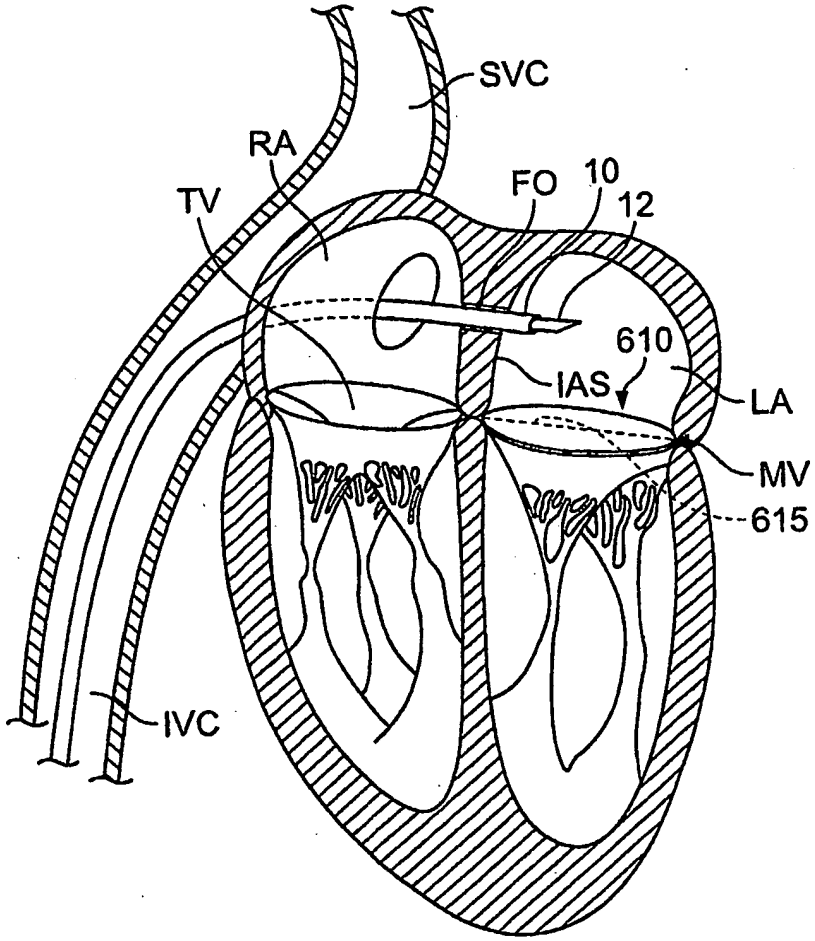

FIG. 6A

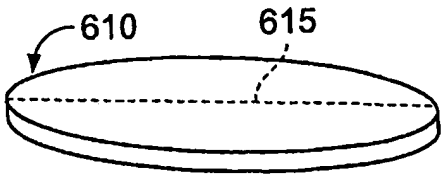

FIG. 6B

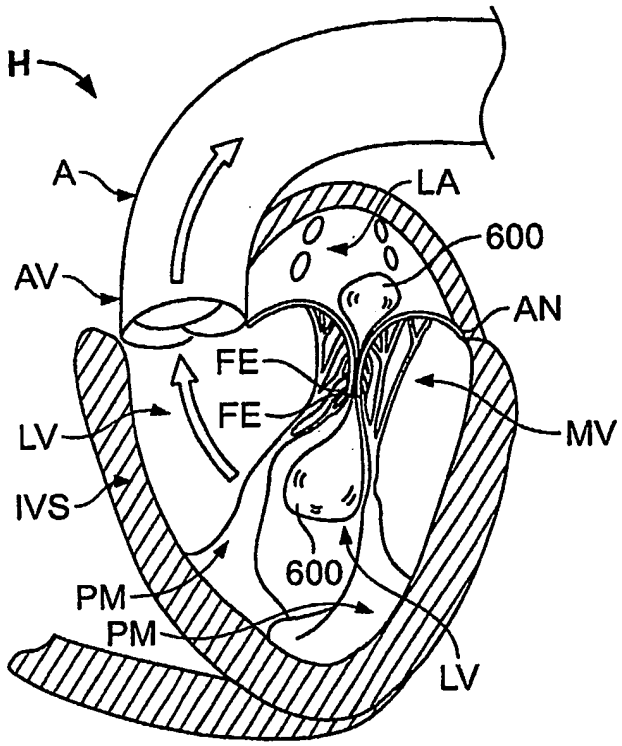

FIG. 7A

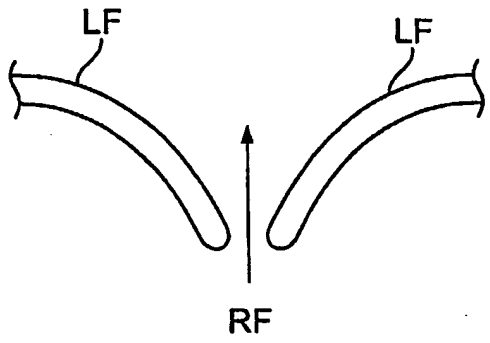

FIG. 7B

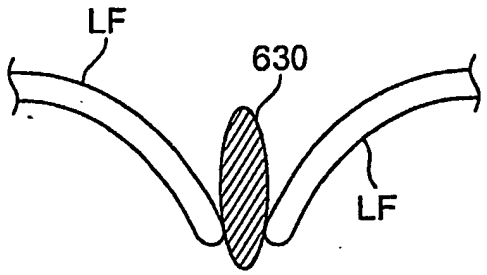

FIG. 7C

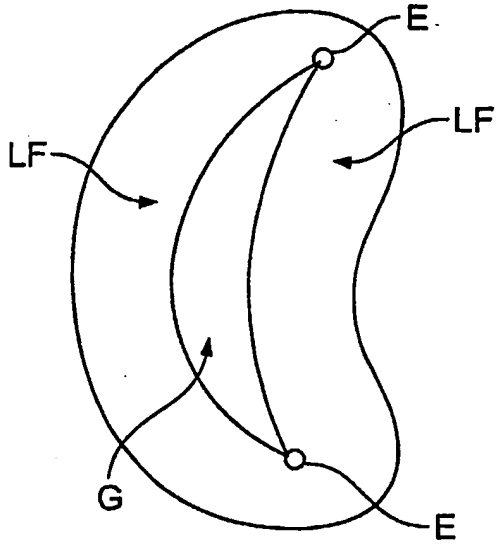

FIG. 7D

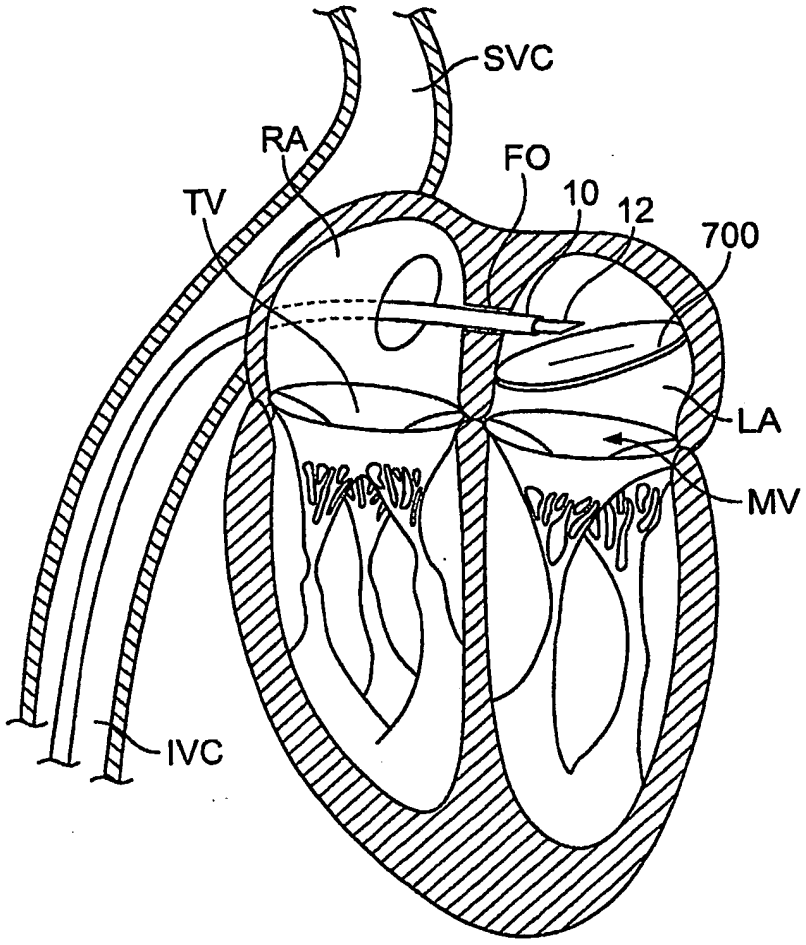

FIG. 8

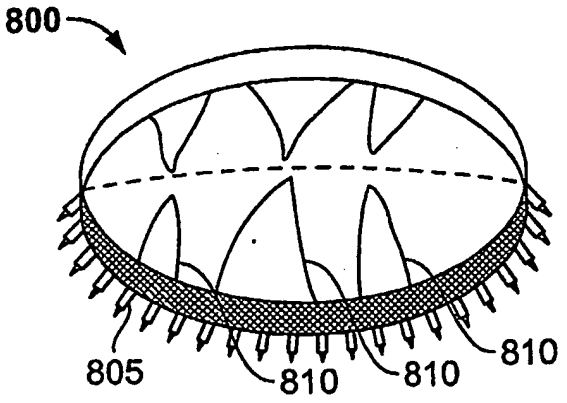

FIG. 9A

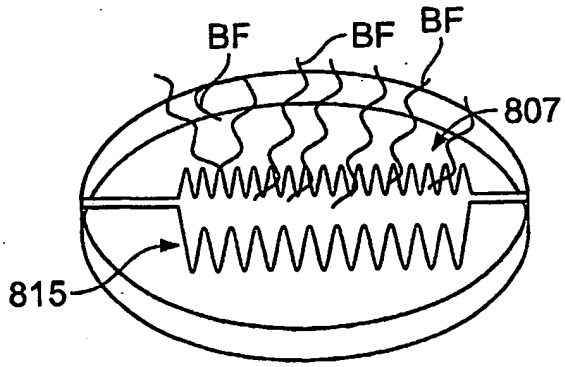

FIG. 9B

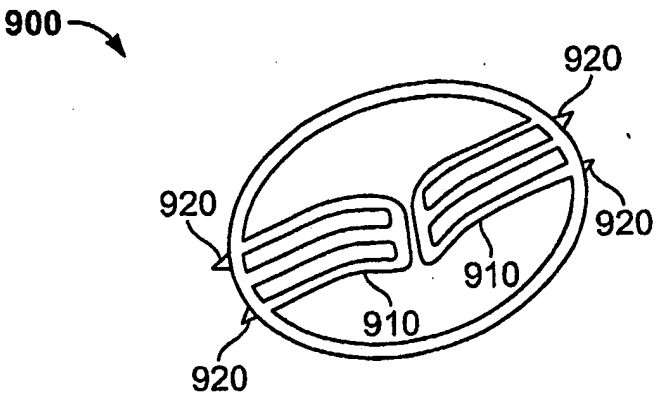

FIG. 10

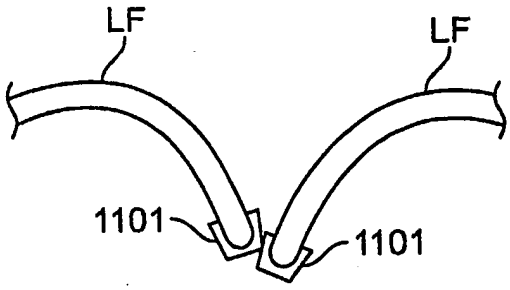

FIG. 11A

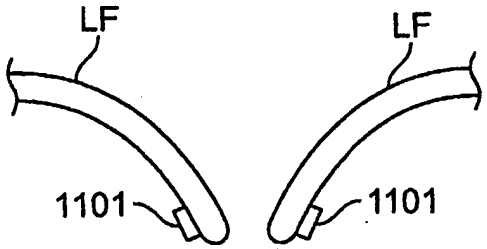

FIG. 11B

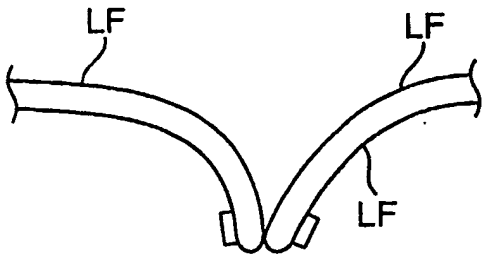

FIG. 11C

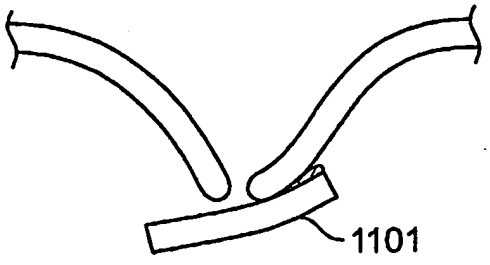

FIG. 11D

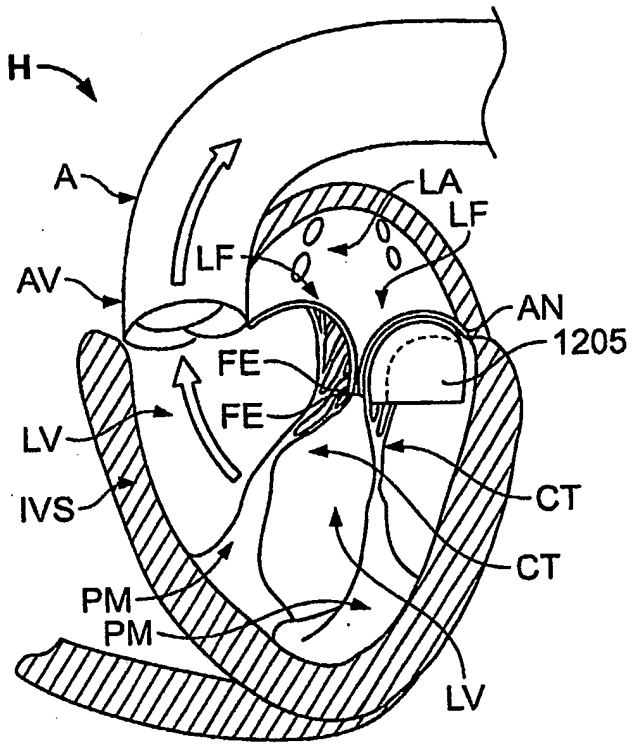

FIG. 12

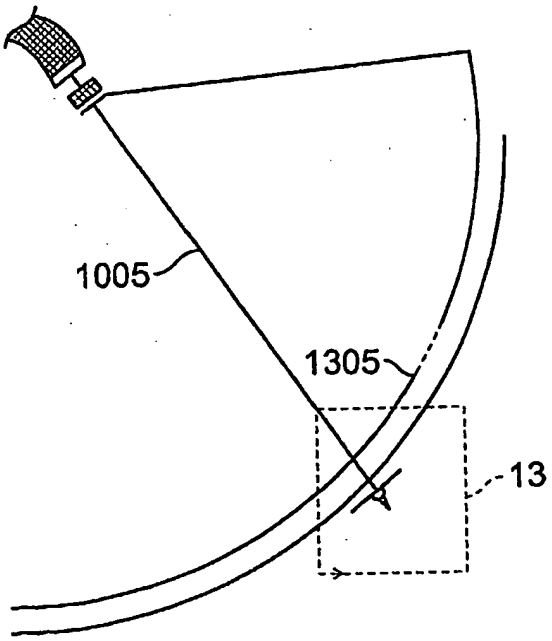

FIG. 13A

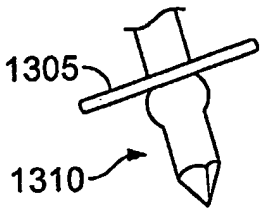

FIG. 13B

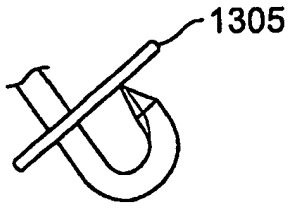

FIG. 13C

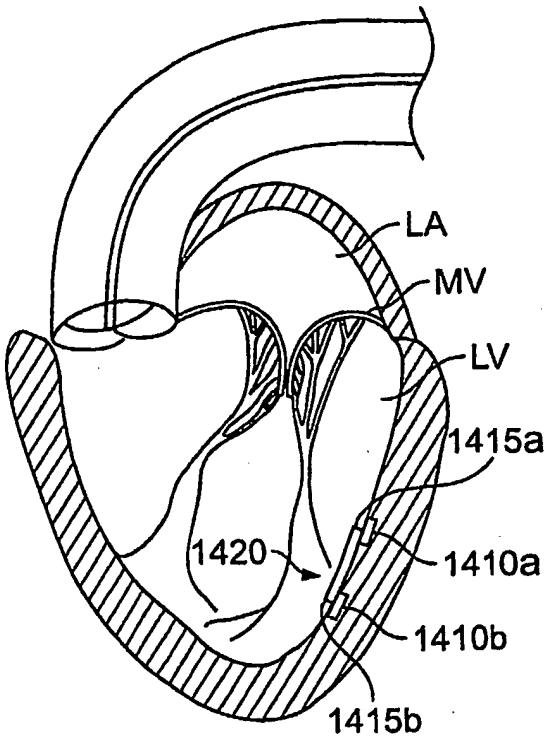

FIG. 14

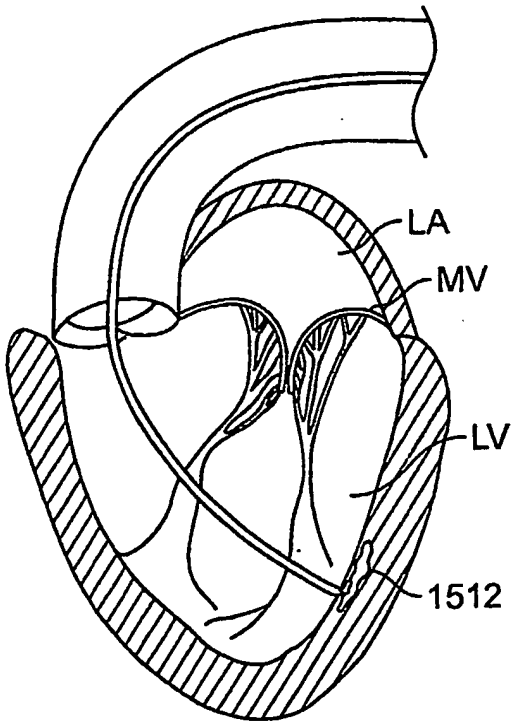

FIG. 15

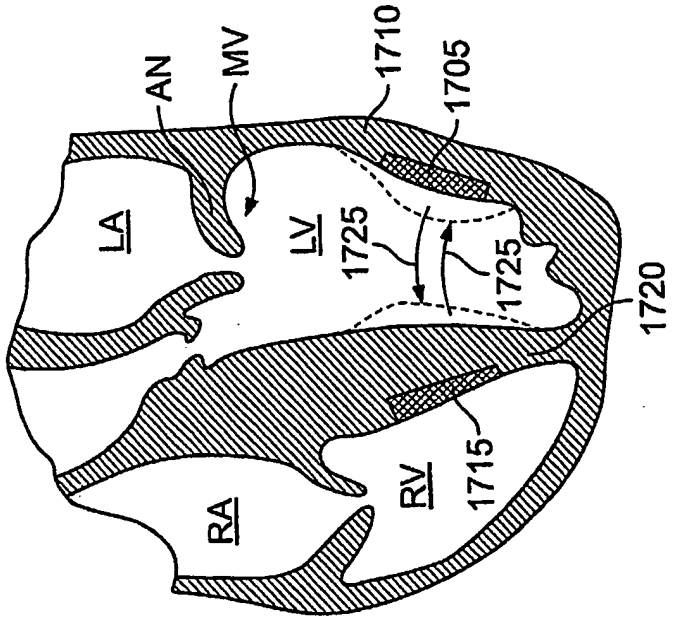
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FIG. 17

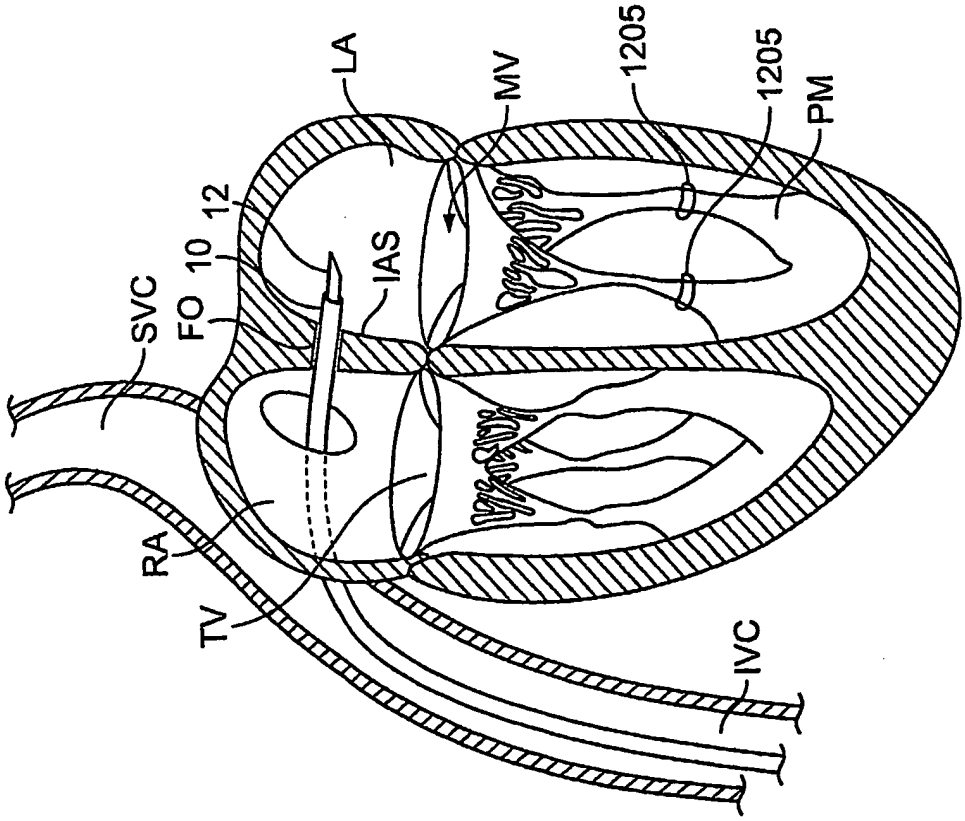
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FIG. 16

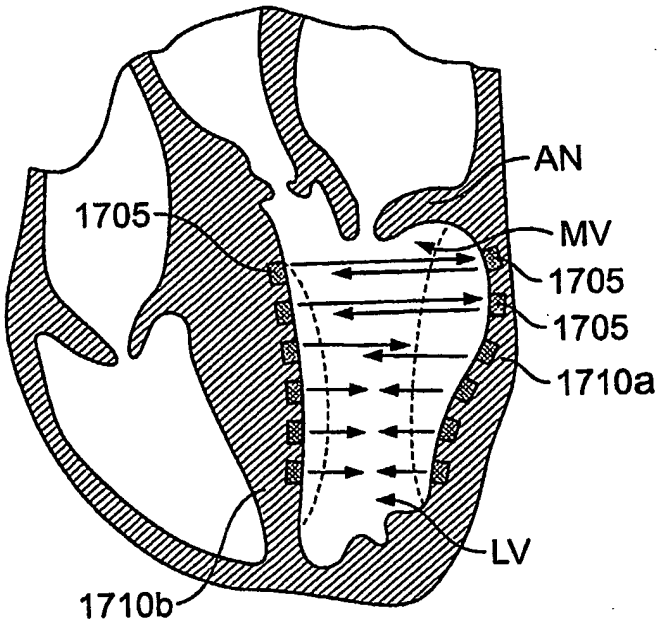

FIG. 18A

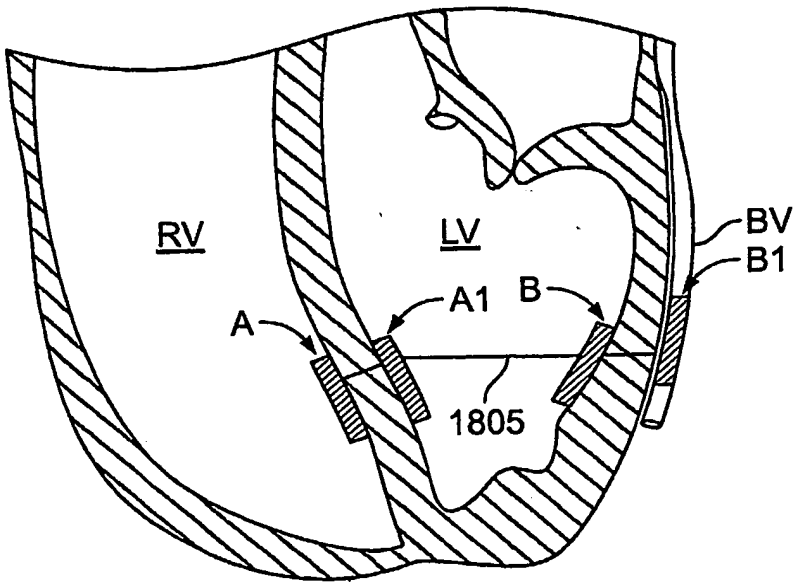

FIG. 18B

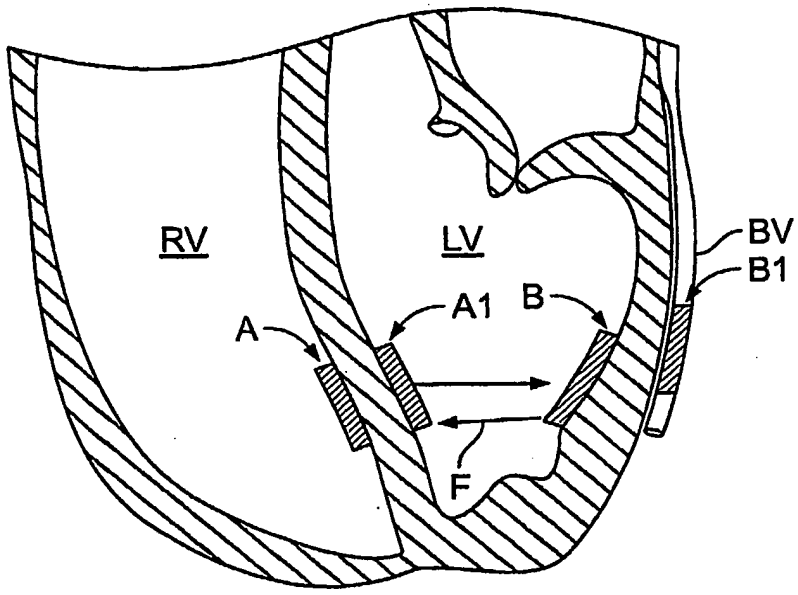

FIG. 18C

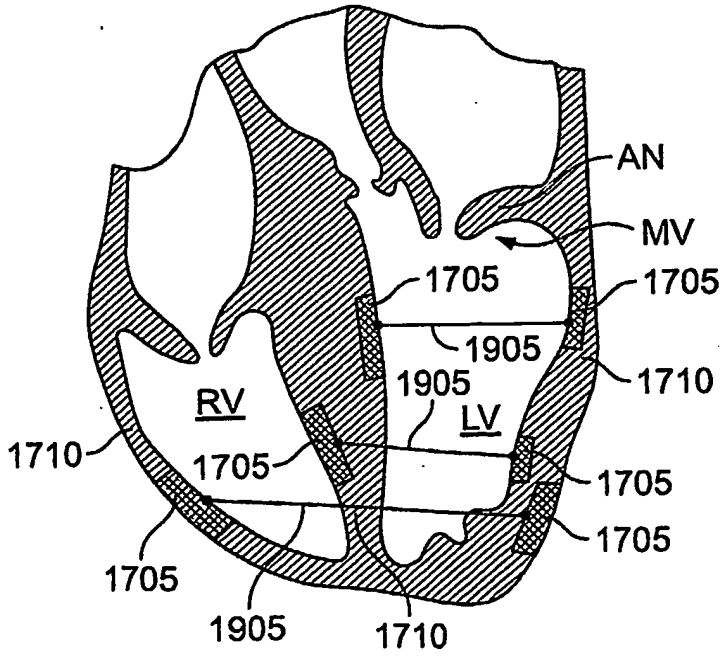

FIG. 19

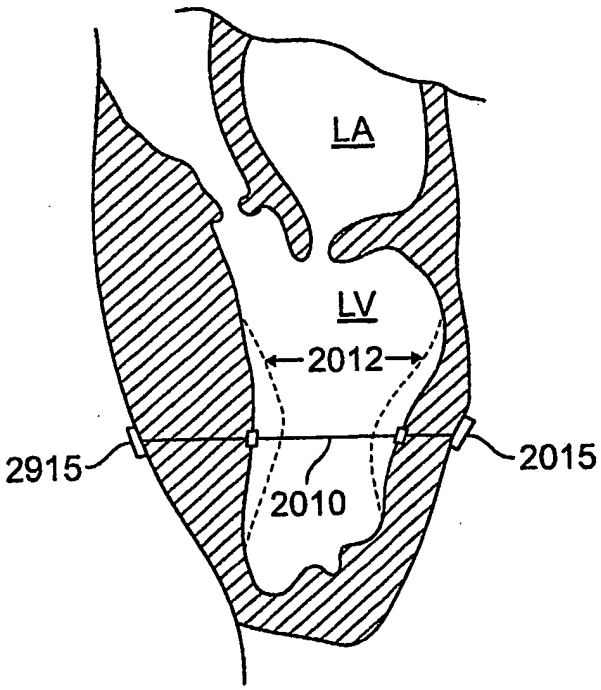

FIG. 20

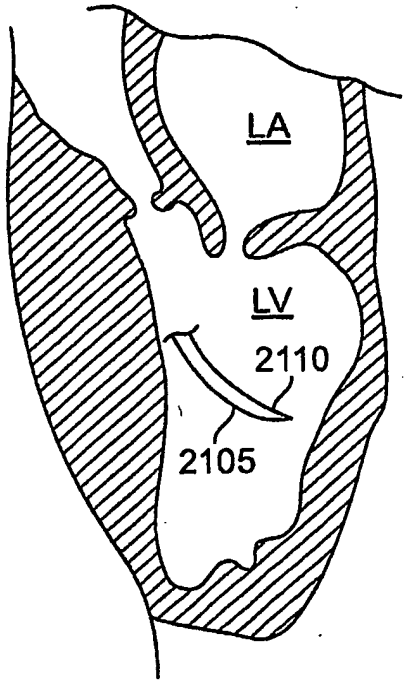

FIG. 21

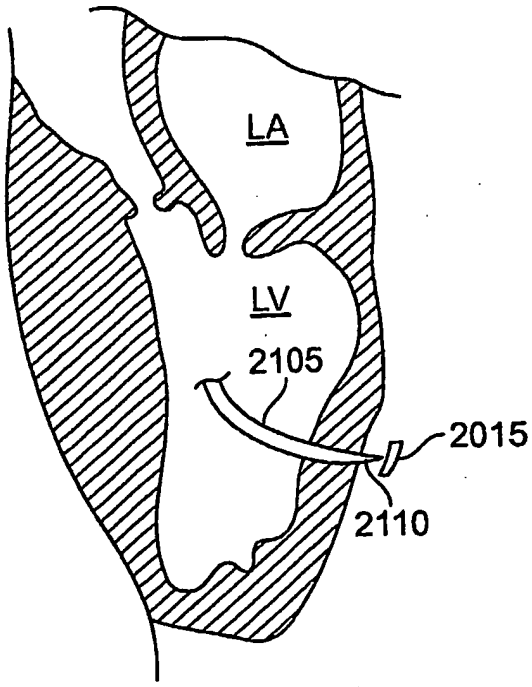

FIG. 22

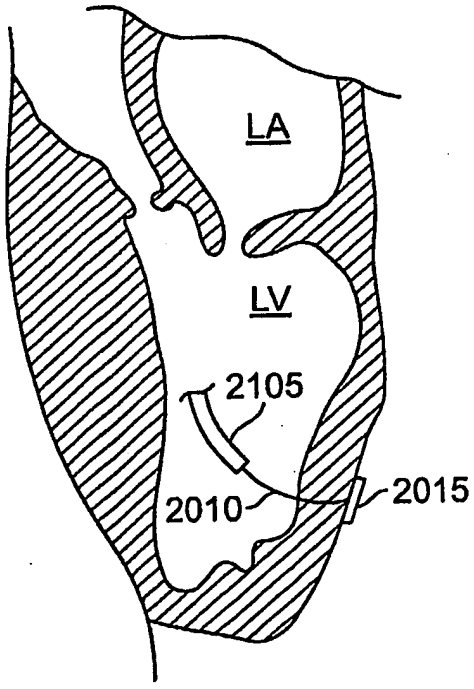

FIG. 23

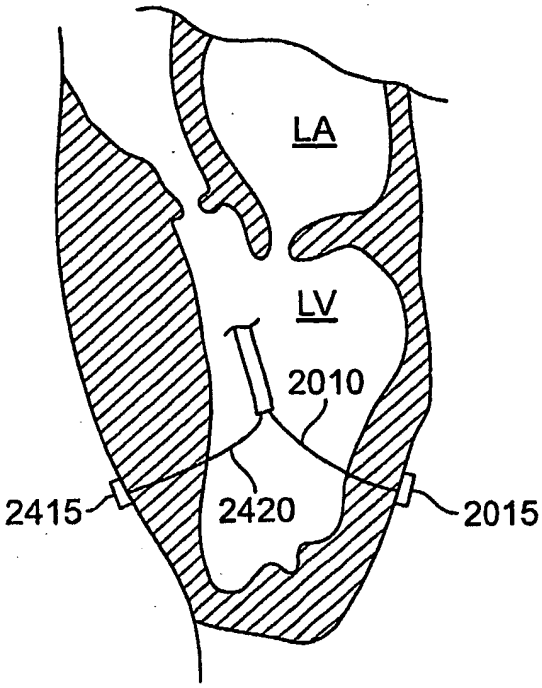

FIG. 24

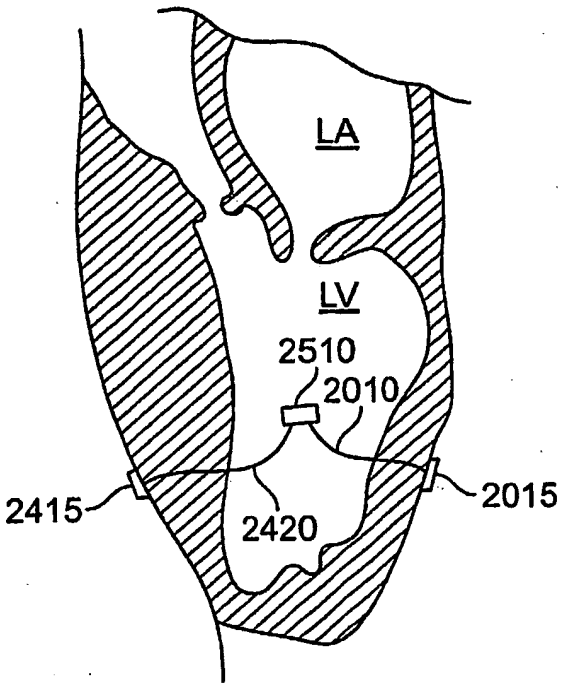

FIG. 25

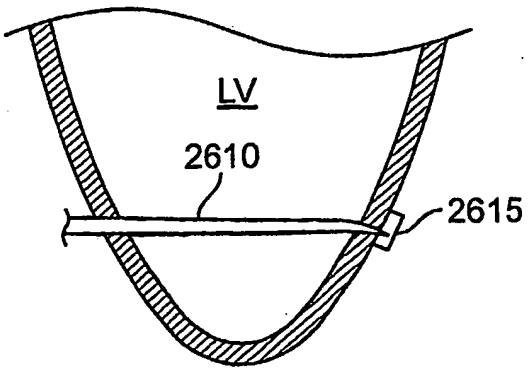

FIG. 26

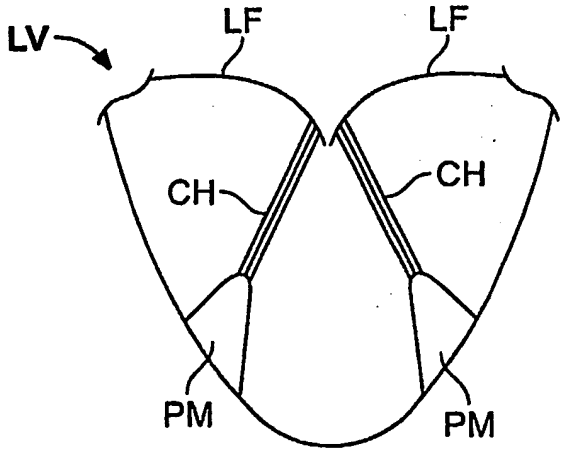

FIG. 27

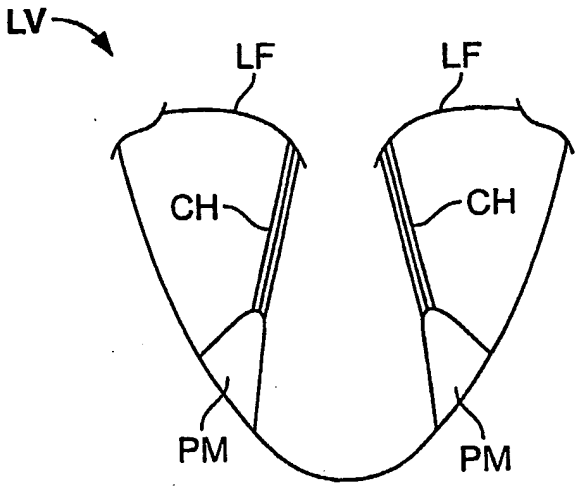

FIG. 28

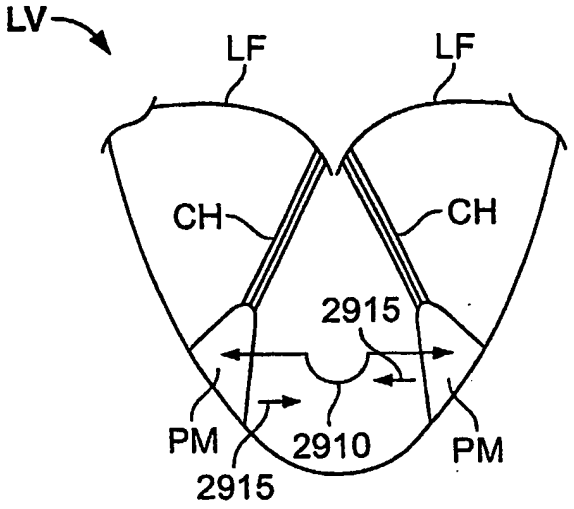

FIG. 29

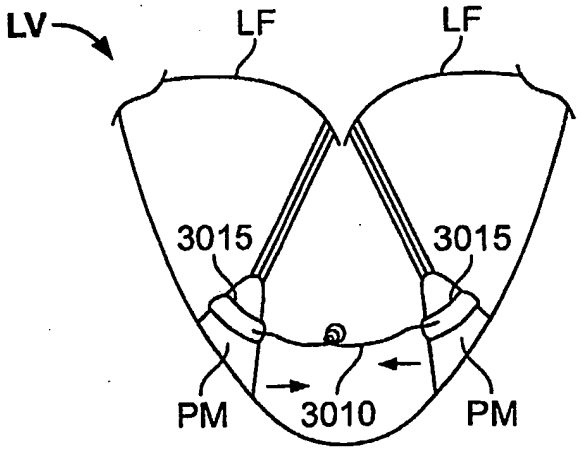

FIG. 30

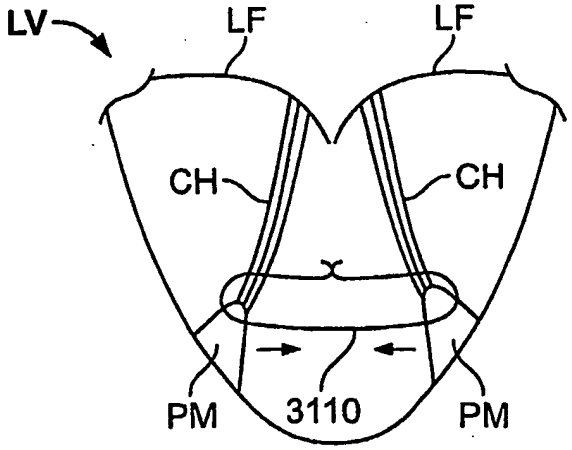

FIG. 31

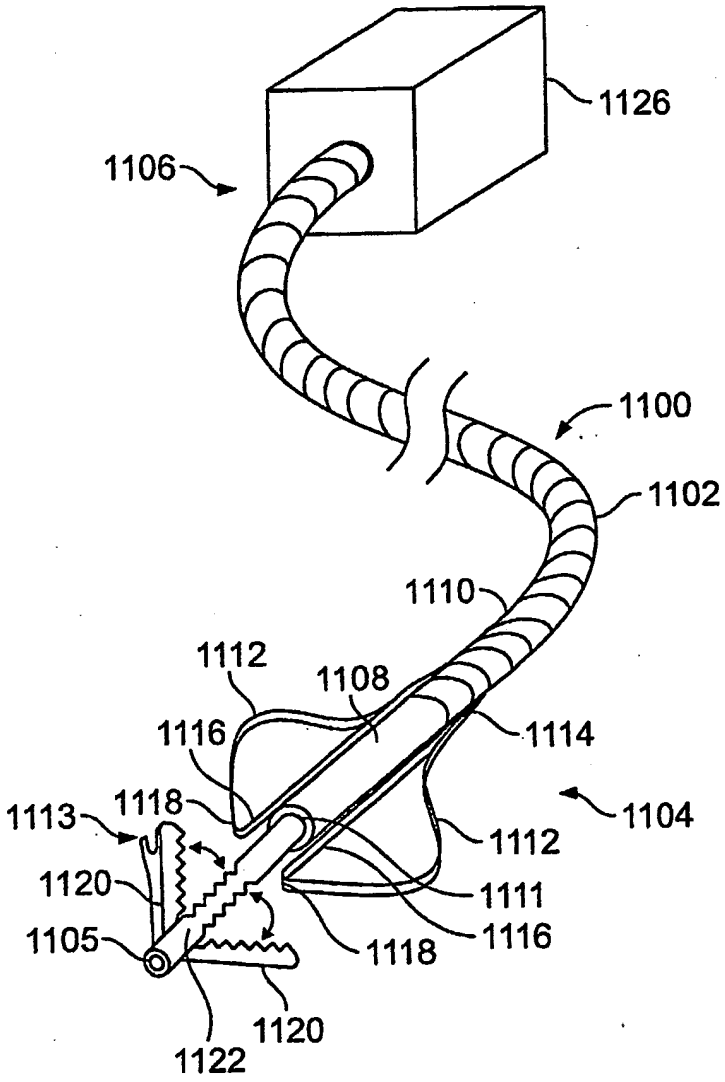
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FIG. 32

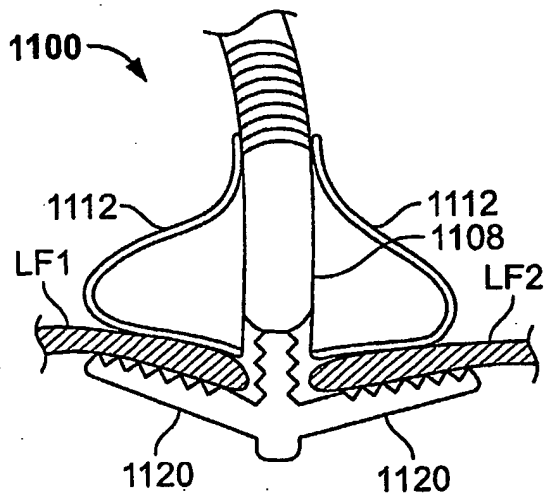

FIG. 33A

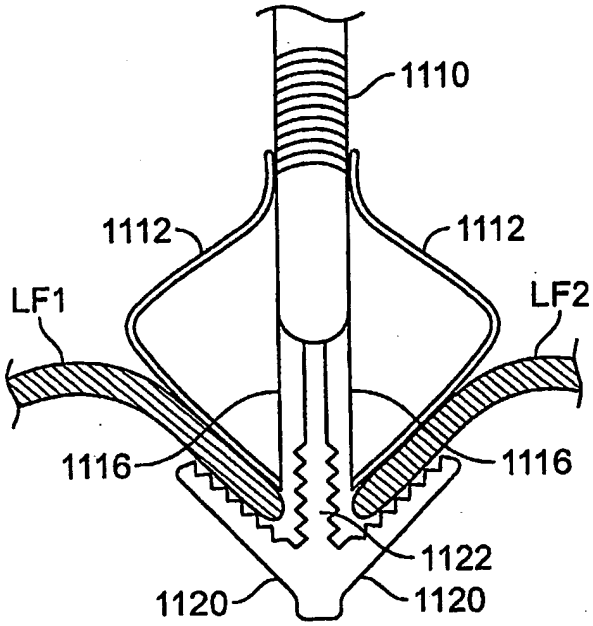

FIG. 33B

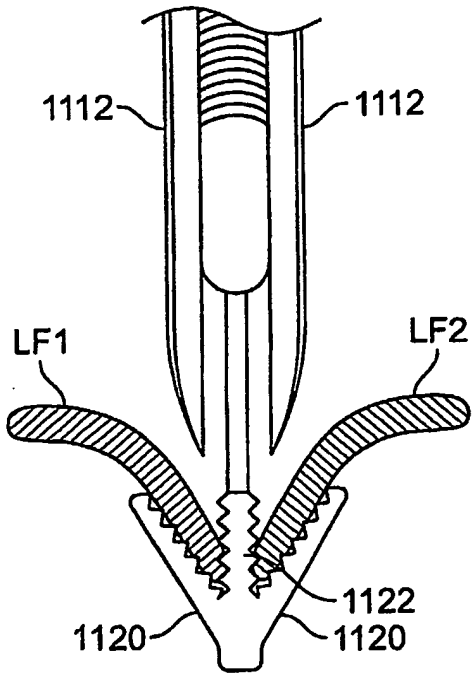

FIG. 33C

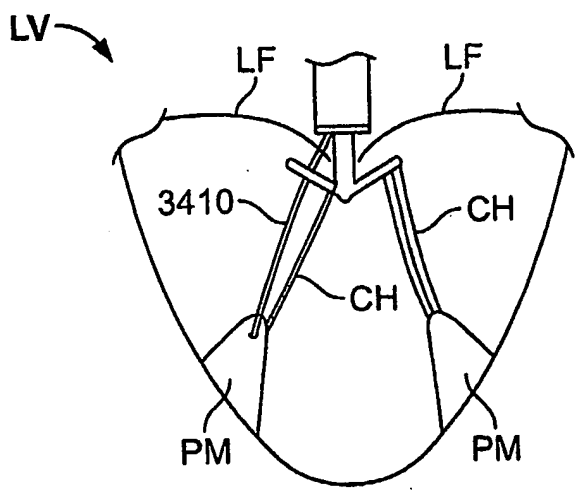

FIG. 34

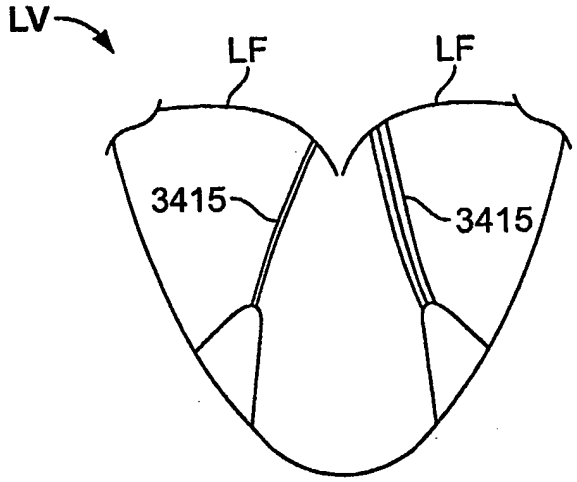

FIG. 35

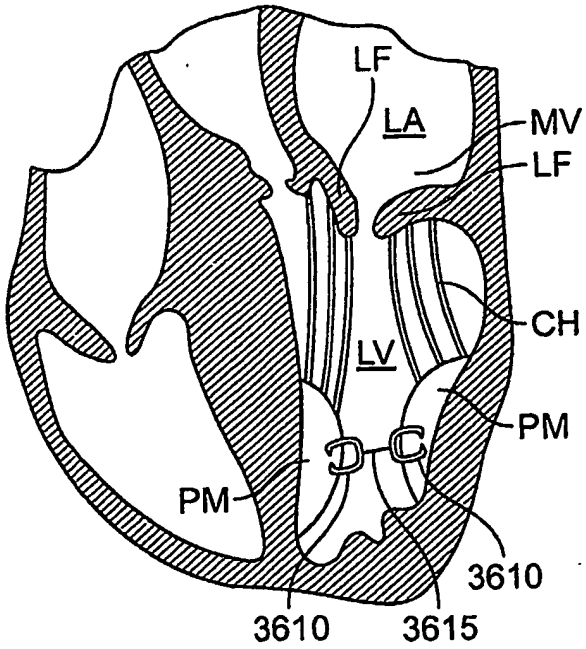

FIG. 36

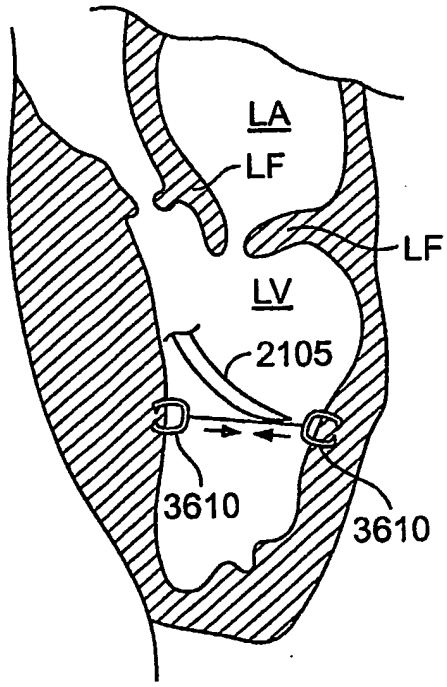

FIG. 37

International application No
PCT/US2006/004368

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/004668 A1 (AKLOG ET AL.) 6 January 2005 (2005-01-06) paragraphs [0077], [0096], [0097]; figures 1a,1b,2a,9a,9b,15a,15b	18
A	WO 03/028558 A (AMPLE MEDICAL CORPORATION) 10 April 2003 (2003-04-10) figures	18
P,X	US 2005/038508 A1 (GABBAY) 17 February 2005 (2005-02-17) the whole document	18

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 June 2006	09/06/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/004368

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-17
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

Information on patent family members

International application No
PCT/US2006/004368

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005004668 A1	06-01-2005	US 2005004665 A1	06-01-2005
		WO 2005002424 A2	13-01-2005
WO 03028558 A	10-04-2003	CA 2455444 A1	10-04-2003
		CA 2462254 A1	10-04-2003
		CN 1610529 A	27-04-2005
		EP 1434621 A2	07-07-2004
		EP 1434542 A2	07-07-2004
		JP 2005504577 T	17-02-2005
		WO 03028802 A2	10-04-2003
US 2005038508 A1	17-02-2005	NONE	

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

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(43) International Publication Date
2 November 2006 (02.11.2006)

(10) International Publication Number
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(51) International Patent Classification:
A61B 19/00 (2006.01)

(21) International Application Number:
PCT/US2006/015941

(22) International Filing Date: 25 April 2006 (25.04.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/674,931 25 April 2005 (25.04.2005) US

(71) Applicant *(for all designated States except US)*: **EVALVE, INC.** [US/US]; 4045 Campbell Avenue, Menlo Park, California 94025 (US).

(72) Inventors; and

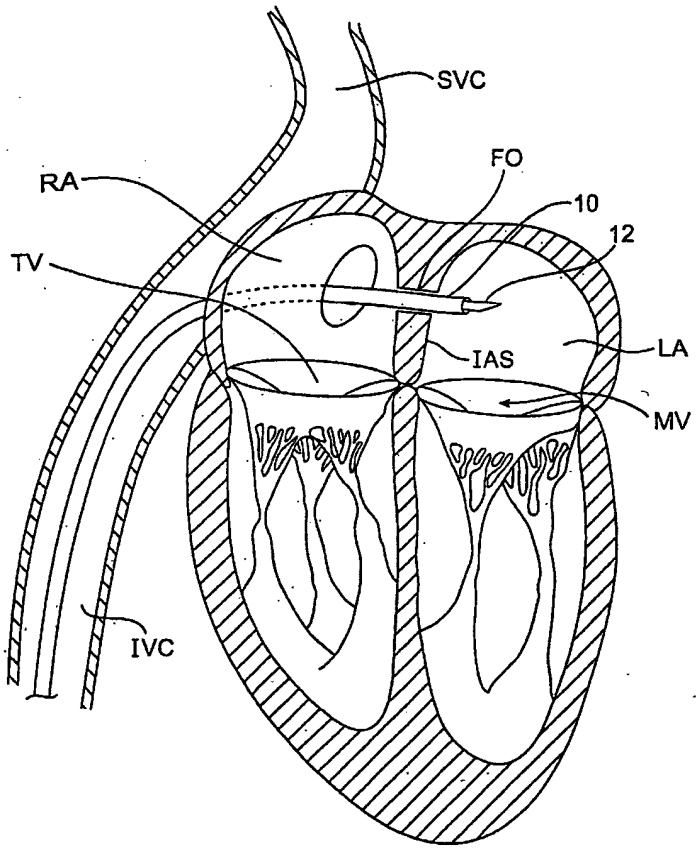
(75) Inventors/Applicants *(for US only)*: **ST. GOAR, Frederick** [US/US]; 2 Frederick Court, Menlo Park, California 94025 (US). **FANN, James** [US/US]; 65 Prado Court, Portola Valley, California 94028 (US). **DEEM, Mark** [US/US]; 685 Sierra Avenue, Mountain View, California 94041 (US). **GIFFORD III, Hanson** [US/US]; 3180 Woodside Road, Woodside, California 94062 (US). **DIECK, Martin** [US/US]; 21105 Hazelbrook Drive, Cupertino, California 95014 (US). **MARTIN, Brian** [US/US]; 315 Alder Road, Boulder Creek, California 95006 (US). **FAN, Sylvia** [US/US]; 1336 Capuchino Avenue, Burlingame, California 94010 (US). **GOLDFARB, Eric** [US/US]; 140 Jersey Street, San Francisco, California 94114 (US). **DELL, Kent** [US/US]; 1131 Grand Avenue, Redwood City, California 94061 (US). **POWELL, Ferolyn** [US/US]; 55 Caselli Avenue, San Francisco, California 94114 (US).

(74) Agents: **HERNANDEZ, Fred** et al.; FISH & RICHARDSON P.C., 12390 El Camino Real, San Diego, California 92130 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV,

[Continued on next page]

(54) Title: DEVICE AND METHODS FOR ENDOSCOPIC ANNULOPLASTY



(57) Abstract: The methods, devices, and systems are provided for performing endovascular repair of atrioventricular and other cardiac valves in the heart. Regurgitation of an atrioventricular valve, particularly a mitral valve, can be repaired by modifying a tissue structure selected from the valve leaflets, the valve annulus, the valve chordae, and the papillary muscles. These structures may be modified by suturing, stapling, snaring, or shortening, using interventional tools which are introduced to a heart chamber. The tissue structures can be temporarily modified prior to permanent modification. For example, opposed valve leaflets may be temporarily grasped and held into position prior to permanent attachment. In one aspect, a structure is deployed in a gutter region of the valve annulus to modify the shape of the valve.

WO 2006/116558 A2

LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DEVICE AND METHODS FOR ENDOSCOPIC ANNULOPLASTY

REFERENCE TO PRIORITY DOCUMENT

This application claims priority of co-pending U.S. Provisional Patent Application Serial No. 60/674,931 entitled " DEVICE AND METHODS FOR ENDOSCOPIC ANNULOPLASTY", filed April 25, 2005. Priority of the aforementioned filing dates is hereby claimed, and the disclosure of the Provisional Patent Application is hereby incorporated by reference in their entirety.

This application is a continuation-in-part of U.S. Application Serial No. 10/820,581 entitled "METHODS AND APPARATUS FOR CARDIAC VALUE REPAIR", filed April 7, 2004, which is a continuation of U.S. Patent Application No. 10/635,776, filed August 5, 2003, which is a continuation of U.S. Patent Application No. 09/544,930, filed April 7, 2000, now U.S. Patent No. 6,629,534, which claimed the benefit under 35 U.S.C. 119(e) of U.S. Provisional Patent Application No. 60/128,690, filed on April 9, 1999 under 37 CFR 1.78(a). The full disclosures of the aforementioned applications are incorporated herein by reference.

BACKGROUND

The present disclosure relates generally to medical methods, devices, and systems. In particular, the present disclosure relates to methods, devices, and systems for the endovascular or minimally invasive surgical repair of the atrioventricular valves of the heart, particularly the mitral valve.

Mitral valve regurgitation is characterized by retrograde flow from the left ventricle of a heart through an incompetent mitral valve into the left atrium. During a normal cycle of heart contraction (systole), the mitral valve acts as a check valve to prevent flow of oxygenated blood back into the left atrium. In this way, the oxygenated blood is pumped into the aorta through the aortic valve.

Regurgitation of the valve can significantly decrease the pumping efficiency of the heart, placing the patient at risk of severe, progressive heart failure.

Mitral valve regurgitation can result from a number of different mechanical defects in the mitral valve. The valve leaflets, the valve chordae which connect the leaflets to the papillary muscles, or the papillary muscles themselves may be damaged or otherwise dysfunctional. Commonly, the valve annulus may be damaged, dilated, or weakened limiting the ability of the mitral valve to close adequately against the high pressures of the left ventricle.

The most common treatments for mitral valve regurgitation rely on valve replacement or strengthening of the valve annulus by implanting a mechanical support ring or other structure. The latter is generally referred to as valve annuloplasty. A recent technique for mitral valve repair which relies on suturing adjacent segments of the opposed valve leaflets together is referred to as the "bow-tie" or "edge-to-edge" technique. While all these techniques can be very effective, they usually rely on open heart surgery where the patient's chest is opened, typically via a sternotomy, and the patient placed on cardiopulmonary bypass. The need to both open the chest and place the patient on bypass is traumatic and has associated morbidity.

For these reasons, it would be desirable to provide alternative and additional methods, devices, and systems for performing the repair of mitral and other cardiac valves, including the tricuspid valve which is the other atrioventricular valve. Such methods, devices, and systems should preferably not require open chest access and be capable of being performed endovascularly, i.e., using devices which are advanced to the heart from a point in the patient's vasculature remote from the heart. Still more preferably, the methods, devices, and systems should not require that the heart be bypassed, although the methods, devices, and systems should be useful with patients who are bypassed and/or whose heart may be temporarily stopped by drugs or other techniques.

SUMMARY

The present disclosure provides methods, devices, and systems for the endovascular repair of cardiac valves, particularly the atrioventricular valves which inhibit back flow of blood from a heart ventricle during contraction (systole), most particularly the mitral valve between the left atrium and the left ventricle. By "endovascular," it is meant that the procedure(s) are performed with interventional tools, guides, and supporting catheters and other equipment introduced to the heart chambers from the patient's arterial or venous vasculature remote from the heart. The interventional tools and other equipment may be introduced percutaneously, i.e., through an access sheath, or may be introduced via a surgical cut down, and then advanced from the remote access site through the vasculature until they reach the heart. Thus, the procedures will generally not require penetrations made directly through the exterior heart muscle, i.e., myocardium, although there may be some instances where penetrations will be made interior to the heart, e.g., through the interatrial septum to provide for a desired access route. While the procedures will usually be percutaneous and intravascular, many of the tools will find use in minimally invasive and open surgical procedures as well that includes a surgical incision or port access through the heart wall. In particular, the tools for capturing the valve leaflets prior to attachment can find use in virtually any type of procedure for modifying cardiac valve function.

The atrioventricular valves are located at the junctions of the atria and their respective ventricles. The atrioventricular valve between the right atrium and the right ventricle has three valve leaflets (cusps) and is referred to as the tricuspid or right atrioventricular valve. The atrioventricular valve between the left atrium and the left ventricle is a bicuspid valve having only two leaflets (cusps) and is generally referred to as the mitral valve. In both cases, the valve leaflets are connected to the base of the atrial chamber in a region referred to as the valve annulus, and the valve leaflets extend generally downwardly from the

annulus into the associated ventricle. In this way, the valve leaflets open during diastole when the heart atria fill with blood, allowing the blood to pass into the ventricle. During systole, however, the valve leaflets are pushed together and closed to prevent back flow of blood into the atria. The lower ends of the valve leaflets are connected through tendon-like tissue structures called the chordae, which in turn are connected at their lower ends to the papillary muscles. Interventions described herein may be directed at any one of the leaflets, chordae, annulus, or papillary muscles, or combinations thereof. It will be the general purpose of such interventions to modify the manner in which the valve leaflets coapt or close during systole so that back flow or regurgitation is minimized or prevented. While the procedures will be most useful with the atrioventricular valves, at least some of the tools described hereinafter may be useful in the repair of other cardiac valves, including the aortic valve.

The methods described herein will usually comprise accessing a patient's vasculature at a location remote from the heart, advancing an interventional tool through the vasculature to a ventricle and/or atrium, and engaging the tool against a tissue structure which forms or supports the atrioventricular valve. By engaging the tool against the tissue structure, the tissue structure is modified in a manner that reduces valve leakage or regurgitation during ventricular systole. The tissue structure may be any of one or more of the group consisting of the valve leaflets, chordae, the valve annulus, and the papillary muscles, atrial wall, ventricular wall or adjacent structures. Optionally, the interventional tool will be oriented relative to the atrioventricular valve and/or tissue structure prior to engaging the tool against the tissue structure. The interventional tool may be self-orienting (e.g., pre-shaped) or may include active mechanisms to steer, adjust, or otherwise position the tool. Alternatively, orientation of the interventional tool may be accomplished in whole or in part using a separate guide catheter, where the guide catheter may be pre-shaped and/or include active steering or other positioning means such as those devices set forth in

United States Patent Application serial numbers 10/441,753 filed May 19, 2003, 10/441,508 filed May 19, 2003 and 10/441,687 filed May 19, 2003, all of which are expressly incorporated by reference herein. In all cases, it will usually be desirable to confirm the position prior to engaging the valve leaflets or other tissue structures. Such orienting step may comprise positioning the tool relative to a line of coaptation in the atrioventricular valve, e.g., engaging positioning elements in the valve commissures and confirming the desired location using a variety of imaging means such as MRI, intracardiac echocardiography (ICE), transesophageal echo (TEE), fluoroscopy, endoscopy, intravascular ultrasound (IVUS) and the like.

In a first aspect, the tissue structure comprises the valve leaflets and the engaging step comprises attaching one or more opposed points on or along the valve leaflets together. In the case of the bicuspid mitral valve, the attachment points may be located at or near the center of each leaflet, creating a generally symmetric structure with two openings, i.e., between the attachment point(s) and each of the two commissures. Alternatively, the attachment points may be close to each of the commissures. Both will effectively reduce the area in which the valve can open. In the case of the tricuspid valve, any two of the three leaflets can be partially or totally closed together or all three may be partially closed together.

In both cases, the attachment of the valve leaflets may be performed in a variety of ways, including suturing, clipping, stapling, riveting, gluing, fusing, or the like. While each of these approaches may differ significantly in the protocols and devices used for performing them, the end result will be the same, i.e., improved ability of the atrioventricular valve to close against the elevated pressures within the ventricle during systole. In order to improve apposition of the valve leaflets, it may be preferred to attach the leaflets at a point spaced inwardly from the free edge of the leaflet. Usually, the attachment point within the valve leaflet will be located from 1 mm to 4 mm inward from the free edge.

It will frequently be desirable to stabilize the interventional tool relative to the valve leaflets and other heart tissue structures at least some points during the interventional procedure. In a broad sense, such stabilization is intended primarily to couple motion of the interventional tool to the motion of the heart so that the tool may then engage the valve leaflets or other target tissue structures with minimum differential motion. The stabilization may be achieved either through the interventional tool or through a guide catheter or other platform which is used to deliver the interventional tool. In both cases, stabilization will usually be achieved by engaging a tissue structure of the heart, such as the interatrial septum, the atrial wall, the valve annulus, the valve chordae, the papillary muscles, or the like. For antegrade approaches, immobilization of either the guide catheter, the interventional tool, or both relative to the valve annulus or valve commissures will be particularly effective. For retrograde approaches, immobilization against the papillary muscles, the chordae, or the valve leaflets themselves may be particularly effective. Stabilization should be distinguished from valve capture which is usually performed after the interventional tool and/or guide catheter have been stabilized within the heart. Thus, the methods may comprise up to four separate steps or phases prior to valve affixation. First, the interventional tool and/or guide catheter may be positioned, either actively or passively. Second, the interventional tool and/or guide catheter may be stabilized within the heart. Next, the interventional tool may be used to capture the valve leaflets. Then, prior to affixation, the valve leaflets may be positioned and, if necessary, repositioned in order to determine that a particular coaptation and affixation are capable of inhibiting the valve regurgitation. Finally, once adequate regurgitation inhibition has been confirmed, the valve leaflets may be affixed in any of the manners described below.

In a particular approach, the interventional tool may be stabilized by mechanically fixing the shape of the tool after the tool has been advanced to a position proximate the atrioventricular valve. For example, the interventional tool

can comprise a plurality of linked elements which can be locked into place, e.g., a "goose-neck" device. Such mechanically lockable devices may be used by themselves or in conjunction with any of the other stabilization devices described herein.

When attaching portions of the valve leaflets together, it will frequently be desirable to temporarily capture the valve leaflets before implementing the final attachment step. For example, the leaflets can be captured using forceps or other graspers introduced as part of or separately from the interventional tool. After capturing the valve leaflets, flow through the valve can be observed by conventional cardiac imaging techniques, such as trans-esophegeal echocardiography (TEE), intracardiac echocardiography (ICE) or other ultrasonic imaging technique, fluoroscopy, angioscopy, catheter based magnetic resonance imaging (MRI), computed tomography (CT) and the like. By thus observing the flow through the valves, and more importantly whether or not back flow or regurgitation continues or has been sufficiently inhibited, the desired attachment configuration for the leaflets can be determined. If continued regurgitation is observed, the valve leaflets may be repositioned and the presence or absence of regurgitation again determined. Such repositioning steps may be continued until a position is identified in which the regurgitation is sufficiently inhibited. Additionally, other considerations, such as position of the attachment within the leaflet, stress placed on the leaflet, and other factors can be visualized before deciding on the final attachment point(s). In a preferred example, the valve leaflets may be coapted by a grasping instrument which also has a fixation mechanism, such as stapling, suturing, clipping or riveting as previously described, so that once a desirable attachment configuration is temporarily achieved, the final attachment can be made using the same instrument. Grasping of the valve leaflets can be accomplished using articulated graspers, vacuum-assisted graspers, grasping pins, or other temporary attachment modes as described in more detail below. After the leaflets are in the desired

configuration, they may be permanently secured together by any of the techniques described above.

In a second aspect, the tissue structure comprises the chordae and the engaging step comprises linking opposed chordae together, i.e., chordae attached to different valve leaflets. Usually, the chordae will be partially gathered or coupled together using a suture or other loop structure. In some instances it may be desirable to closely tie the chordae together at one or more locations.

In a third aspect, the tissue structure comprises the chordae and the engaging step comprises applying energy to shorten the chordae. Particular forms of heat energy, most particularly radiofrequency energy, have been found to be able to modify and shrink collagen so that supporting chordae may be tightened. By applying energy to shorten one or more of the chordae attaching either or both (or all three in the case of the tricuspid valve) valve leaflets, the flow through the atrioventricular valve can be modified and regurgitation minimized. In one aspect, the chordae will be initially grasped or captured and manipulated to temporarily apply tension to the valve leaflets. The effect of such temporary shortening can then be visually assessed and, if a desired improvement in valve performance is observed, energy can be applied to shorten the chordae. In many cases, however, it may be preferable to apply a clip, ring, suture loop, or other mechanical element to permanently twist, plicate, or otherwise shorten the chordae, as described elsewhere herein.

In a fourth aspect, the tissue structure comprises the valve annulus and the engaging step comprises circumferentially tightening or shortening the annulus. In a preferred technique, the annulus will be strengthened by positioning and attaching a supporting structure over the annulus in a manner broadly analogous to the open surgical placement of an annuloplasty ring. Alternatively, the annulus can be tightened by surgical plication techniques, or in some instances by shrinking tissue within the annulus by applying radiofrequency

energy as generally described above in connection with shortening of the chordae.

In a fifth aspect, the tissue structure comprises the papillary muscles and the engaging step comprises capturing and drawing opposed points or portions of the papillary muscles together. This approach is similar in many respects to capture of the chordae, and will generally comprise suturing or otherwise forming a linkage between the opposed portions of the papillary muscles. As with the chordae, it will generally not be desirable to fully close the papillary muscles together, although in some instances such an approach may also find use.

In all the aspects of the method described above, the heart will usually remain beating while the interventional tool is engaged against the tissue structure. When the heart is beating, however, it may be desirable to temporarily stop valve action during at least a portion of the procedure, particularly to facilitate grasping of the valve leaflets when such a technique is being employed. The valve action can be slowed temporarily by decreasing the heart rate with intravenous infusion of a beta blocker, such as esmolol, or can be completely stopped for a brief time, e.g., five to ten seconds, by infusion of a drug, such as adenosine. Alternatively, the valve action can be stopped by temporarily raising the pressure in the associated ventricle to a pressure above that in the atrium during diastole. While the heart will continue to beat, the motion of the valve leaflets opening and closing will be stopped to facilitate grasping. As a further alternative, it will be possible to mechanically restrain the leaflets directly or by capturing the chordae, as described in more detail below. While such an approach may be effective for some purposes, the difficulty in capturing the valve leaflets initially may still be present.

While the methods described herein are particularly desirable since they permit interventions to occur without stopping the heart, they may also be used with patients undergoing cardiopulmonary bypass. Such cardiopulmonary bypass can be achieved by any presently available technique, including both

conventional systems and recently developed endovascular bypass systems, such as those available from Heartport, Inc., Redwood City, California.

During the procedures performed while the heart is beating, it will often be desirable to stabilize the interventional tool against one or more cardiac structures prior to grasping the leaflets with the interventional tool. Such stabilization will lessen the relative motion between the tool and the structure. Stabilization mechanisms may be separate from or integral with any part of the system or device, including but not limited to guidewires, guiding catheters and interventional tools. Likewise, the stabilization mechanisms may provide one or more additional functions in the tissue modification procedure, such as steering, orientation assessment, grasping, coaptation, adjustment and fixation. Therefore, many components in the system may have dual purposes.

Coaptation may be performed by a number of methods, such as capturing the leaflets or by releasably capturing the chordae attached to each leaflet. An exemplary capture device will comprise a snare, or a pair of snares, which are advanced through the chordae to capture or entangle individual chordae. This snare or snares may then be tightened to draw the chordae partially together and limit valve motion, at least partially. After such coaptation is achieved, the valve leaflets, chordae, papillary muscles, or annulus may then be engaged and modified, e.g., the leaflets may be attached, using a separate interventional tool, as described above and elsewhere herein. Alternatively, it will be possible to form a permanent link, bridge, or capture of the chordae if the temporary coaptation appears sufficient to repair valve function. In some instances, it may be sufficient to simply detach the snare or other capture mechanism and leave it in place permanently. In other instances, it will be possible to exchange the snare for a more permanent attachment structure, such as a suture loop or metallic coil. For example, once the snare is in place, if the valve function is acceptably repaired, the snare may be drawn out from the chordae through the placement catheter, where the snare pulls a length of suture in the manner of a

needle passing through tissue. The suture can then be tied or otherwise fastened to form a permanent capture loop for the chordae. Alternatively, a separate attachment structure, such as a metal coil, barb, malecot, or the like, may be advanced around the snared chordae to effect permanent capture, where a structure will be detached and left in place.

The methods described above may be performed using either antegrade or retrograde endovascular access through the vasculature. The following description will describe both antegrade and retrograde access approaches for gaining access to the mitral valve. Mitral valve access is generally more difficult than tricuspid valve access. In a retrograde approach, the interventional tool, optional guiding catheter, and any other supporting devices, will be introduced through distal arterial vasculature and over the aortic arch and into the left ventricle through the aortic valve. Typically, the aortic arch or via a brachial approach will be approached through a conventional femoral artery access route, but could also be approached through the brachial artery, axillary artery, or a carotid artery. When entering the left ventricle, the interventional tool will generally be directed downwardly and away from the mitral valve structure. Thus, the interventional tool will usually be curved or turned so that it approaches the mitral valve from below, usually through the chordae toward the valve annulus. For example, the interventional tool can enter the left ventricle through the aortic valve and then be deflected or otherwise steered to turn 90° to directly approach the mitral valve and chordae. Steering of the tool can be accomplished by deflecting a supporting catheter using pull wires, pre-formed curved catheters, or the like. In some instances, the papillary muscles could be more directly accessed since they generally lie below the aortic valve and inline with the tool as it enters the left ventricle.

Often, it will be desirable to position the interventional tool toward the target tissue structure using a preformed and/or steerable guide catheter. In a retrograde approach, the guide catheter may be placed from an access point,

e.g., the femoral artery at the patient's groin, so that it passes over the aortic arch, through the aortic valve, and into the left ventricle where it will form an access path to the target tissue structure. When the tissue structure is the chordae or valve leaflets, the guide catheter will usually have to be curved or be everted or turned backward so that it can turn the interventional tool around. Additionally, it may be desirable to provide for stabilization of the distal end of the guide catheter. Stabilization may be provided by extendible elements, wires, cages, balloons, or other structures which engage the valve annulus, chordae or ventricular wall portions. Alternatively, two or more stabilizing extensions may be provided to project forwardly from the guide catheter and seat in the valve commissures to position and hold the guide catheter in place. Such extendible elements may also be used to stabilize guidewires, interventional tools and other types of catheter systems. Specific stabilization structures will be described in more detail below.

Access for an antegrade endovascular approach will be through the inferior vena cava or superior vena cava into the right atrium. Such antegrade access may, in itself, be sufficient to perform procedures on the tricuspid valve from the top of the valve. Such procedures, however, will not be described in detail herein. To access the mitral valve, it will be necessary to pass from the right atrium into the left atrium, typically by passing the tool through the interatrial septum. The interatrial septum may be endovascularly penetrated by conventional techniques, typically using a Brockenbrough needle, as described in the valvuloplasty literature. Once the interatrial septum has been penetrated, the interventional tool may be passed into the left atrium so that it approaches the mitral valve from the top. Such an approach will require that the access path turn downward, typically through an angle in the range from 0° to 120°.

The superior vena cava may be accessed through a variety of conventional peripheral access sites, such as the internal jugular vein, while the

inferior vena cava may be accessed through the femoral vein. Such access may be performed percutaneously or by surgical cut down techniques.

As with the retrograde arterial approach, the antegrade venous approach may utilize placement of a guide catheter. With the use of a guidewire, the guide catheter will be configured to pass from the initial access location, through either the superior vena cava or inferior vena cava into the right atrium. The guide catheter will then be adapted to pass through an interatrial penetration and into the left atrium, where it will be pre-shaped or deflected to approach the mitral valve from the top. The guidewire, guide catheter and/or the interventional catheter which carries the interventional tool may be steerable and may optionally have stabilizing elements. For example, in this specific embodiment, the guide catheter may have two or more laterally extensible steering wires and/or a plurality of stabilizing arms which project forwardly and seat around the valve annulus or commissures to hold the guide catheter in place. The interventional tool may then be deployed through the guide catheter to perform the desired valve repair technique.

Systems described herein comprise a guide catheter configured to pass from the remote vasculature of a patient to a position within the heart adjacent to a target atrioventricular or other cardiac valve. The systems further comprise an interventional catheter configured to pass through the guide catheter and to engage the atrioventricular or other cardiac valve and/or associated cardiac structures and an interventional tool on the interventional catheter adapted to modify the atrioventricular or other cardiac valve leaflets, valve annulus, valve chordae or papillary muscles to reduce regurgitation. In particular, the guide catheter can be configured for either an antegrade or retrograde approach to the mitral valve, as described above. The guide catheter may further comprise a stabilizing element for engaging tissue within the heart to reduce relative movement between the guide catheter and the tissue while the heart remains beating. The structure can be any of the cages, wires, or the like, which have

previously been described in connection with the method. Additionally, the interventional catheter may also comprise a stabilizing element for engaging a tissue structure within the heart to reduce relative motion between the interventional catheter and the tissue. The stabilizing element can also be an expansible cage, steering wires, or the like and may include vacuum and/or surface finishes to enhancing coupling. Specific interventional tools include suturing devices, stapling devices, clip-applying devices, radiofrequency electrodes, surgical adhesive applicators, annuloplasty rings, and the like.

Both the interventional tool and the guide catheter may employ stabilizing mechanisms intended to engage a tissue structure within the heart to reduce relative movement between the interventional tool and/or guide catheter relative to the heart, and in particular relative to the atrioventricular valve. The stabilization mechanisms in both cases may be the same. Typically, the stabilization mechanisms will be adapted to engage at least one tissue structure selected from the group consisting of the interatrial septum, the atrial wall, the valve annulus, the valve commissures, the valve chordae, and the papillary muscles. For example, the stabilizing mechanism may comprise one or more extensible wires which are deployable radially outwardly to engage the tissue structure, such as the valve commissures. Alternatively, the stabilizing mechanism could comprise an expansible cage that can be deployed to occupy all or at least a major portion of the atrium above the atrioventricular valve. As a still further alternative, the stabilizing mechanism could be a pair of inflatable balloons which are spaced-apart and adapted to engage the interatrial septum when the interventional tool and/or guide catheter are passed therethrough.

In further specific aspects, the interventional tool may comprise a valve leaflet capture device intended for temporarily holding the valve leaflets prior to modification, e.g., affixation. For example, the valve leaflet capture device may comprise a pair of extensible elements which may be advanced from a distal end of the interventional tool to engage and capture the two mitral valve leaflets or

three aortic valve leaflets. The particular capture tools may grasp the leaflets by pinching, partially or fully penetrating or piercing, and/or suctioning the leaflets. The tools may comprise jawed devices, looped devices, coiled devices or pronged devices, or vacuum devices to grasp and hold the leaflets.

The present disclosure further provides methods for grasping an atrioventricular or other cardiac valve, particularly the mitral valve, to facilitate subsequent intervention or for other purposes. The grasping method comprises capturing chordae attached to at least one leaflet of the valve while the heart is beating. Capture of the chordae from beneath the valve can modify leaflet movement and improve valve function, optionally closing portions of opposed valve leaflets against each other. Usually, chordae attached to valve leaflets (or possibly three valve leaflets in the case of tricuspid valves) are captured simultaneously. For example, one or more snares, such as helical coils, can be advanced into the chordae to capture and immobilize portions thereof. Alternatively, a loop element can be advanced through the valve chordae and tightened in order to modify valve function. In some instances, capture of the chordae can be made permanent and will be sufficient to treat the underlying regurgitation. In other cases, capture of the chordae will be primarily for leaflet coaptation, and the leaflets will be affixed by a subsequent interventional step. Preferably, the subsequent interventional step is performed while the chordae remain captured. The chordae can then be released after the leaflets or other tissue structures have been modified.

The present disclosure still further provides a chordae capture catheter comprising a catheter body having a proximal end and a distal end. Means are provided at or near the distal end of the catheter body for capturing the chordae. A first exemplary means comprises one or more coils which are extensible from the distal end of the catheter and which engage and entangle the chordae when they are advanced therein. A second exemplary capture means comprises a loop element which is extensible from the distal end of the catheter and which is

pre-formed to pass through the chordae on one or both, preferably both valve leaflets in order to draw the chordae together and modify valve function.

A further method according to the present disclosure for grasping an atrioventricular or other cardiac valve leaflets comprises capturing two valve leaflets separately and preferably sequentially. Such capture is effected by a leaflet capture catheter having at least three grasping jaws or prongs. A first valve leaflet is captured between a first pair of prongs, and second valve leaflet is captured between a second pair of prongs. Optionally, the two prong pairs can have a common center prong, typically where the center prong is fixed (immobile) and the two outer prongs pivot in order to provide a pair of adjacent jaw-type graspers. By separately and sequentially grasping the two leaflets, the leaflets can be held in a preferred apposition and the improvement in valve function observed. Alternatively, the leaflets may be grasped simultaneously. If the improvement is adequate, the valves can be permanently affixed in a separate step. Optionally, the leaflet capture catheter can include a device for fixing the valves, e.g., it can carry a clip which can be applied on to the valves as the capture catheter is withdrawn.

The present disclosure still further provides leaflet capture catheters suited for performing the method just described. The catheters comprise a catheter body having a proximal end and a distal end. A leaflet grasper is provided at or near the distal end of the catheter body and includes at least three prongs wherein at least two of the three prongs are pivotable so that they may be separately actuated to separately capture individual leaflets or simultaneously actuated to capture the leaflets together. Optionally, the catheters further comprise means for affixing the valve leaflets after they have been captured, preferably comprising a clip-applier.

The present disclosure further includes leaflet capture catheters and tools which utilize a vacuum for grasping the valve leaflets and manipulating the post leaflets into a desired apposition. Usually, the catheter will have at least two

vacuum channels at a distal end where the channels are preferably separately positionable and independently actuable. In that way, at least two valve leaflets can be separately captured and positioned while the base catheter remains stationary. The catheter may be positioned in an antegrade or retrograde manner with the tool entering between the valve leaflets and optionally between the chordae. The tool and/or catheter may optionally further include modification devices, such as suture appliers, clip appliers, staplers, rivet appliers, adhesive applicators, heating elements for shortening the chordae, and others of the specific interventional tools described hereinafter. Likewise, the present disclosure further includes catheters and tools which include lumens for monitoring pressures within the chambers of the heart, and/or infusion of radiopaque contrast solution.

The present disclosure further includes a method of modifying a heart valve of a patient. The method comprises advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart. The catheter has at least one structure releasably coupled thereto. The method further comprises deploying the structure from the catheter into a gutter on a ventricular side of annulus of the heart valve, the structure adapted to modify the annulus so as to reduce regurgitation in the heart valve; and, in combination with deploying the structure, holding leaflets of the heart valve together so as to reduce regurgitation in the heart valve.

The present disclosure further includes a method of modifying a heart valve of a patient. The method comprises advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the hear. The catheter has an annuloplasty device releasably coupled thereto. The method further comprises performing an intervention on a gutter on a ventricular side of the heart valve to modify an annulus of the heart valve and reduce regurgitation in the heart valve; and in combination with performing an intervention, modifying a spatial relationship between a first valve leaflet and a

second valve leaflet of the heart valve so as to reduce regurgitation in the heart valve.

The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of the left ventricle of a heart showing blood flow during systole with arrows.

Fig. 2 is a schematic illustration of the left ventricle of a heart having prolapsed leaflets in the mitral valve.

Fig. 3 is a schematic illustration of a heart in a patient suffering from cardiomyopathy where the heart is dilated and the leaflets do not meet.

Fig. 3A shows normal closure of the leaflets, while Fig. 3B shows abnormal closure in the dilated heart.

Fig. 4 illustrates mitral valve regurgitation in the left ventricle of a heart having impaired papillary muscles.

Fig. 5 is a schematic illustration showing direct attachment of opposed valve leaflets to reduce valve regurgitation.

Fig. 6 is a schematic illustration showing attachment of valve chordae to treat valve regurgitation.

Figs. 7-8 show exemplary antegrade approaches to the mitral valve from the venous vasculature.

Figs. 9-10 show exemplary retrograde approaches to the mitral valve through the aortic valve and arterial vasculature.

Figs. 11-14 illustrate the use of adjustment wires for steering capability.

Figs. 15A-15D illustrate the use of pre-shaped mandrels to steer a component or structure.

Figs. 16-20, 21A-21C, and 22A-22B depict various orientation assessment tools.

Fig. 23 is a schematic illustration of an interatrial septum stabilization device.

Fig. 24 is a schematic illustration of a catheter shaft designed to provide stabilization against a structure, such as the interatrial septum, or for flexible adjustment and locking stability in various positions.

Fig. 25 is a schematic illustration of an atrial stabilization device.

Figs. 26-29 illustrate stabilization mechanisms which utilize coupling to the valve annulus.

Figs. 30, and 31A-31D illustrate stabilization mechanisms which utilize coupling with the valve commissures and/or leaflets.

Figs. 32A and 32B illustrate mitral valve stabilization using snares for capturing the valve chordae.

Figs. 33A and 33B illustrate an antegrade approach for snaring valve chordae and optionally suturing the chordae together to treat valve regurgitation.

Fig. 34 illustrates an antegrade approach for snaring valve chordae to stabilize the mitral valve.

Figs. 35 and 35A illustrate a snaring catheter particularly intended for capturing valve chordae from a retrograde approach.

Figs. 36A and 36B illustrate use of the catheter Fig. 35 for snaring valve chordae.

Figs. 37 and 38 illustrate a catheter similar to that shown in Figs. 35 and 35A, except that it includes a working channel for introducing interventional catheters and tools to treat the mitral or other atrioventricular valve.

Figs. 39A and 39B illustrate a coil which can be implanted within the valve chordae to stabilize the mitral valve.

Fig. 40 illustrates placement of the coil of Figs. 39A and 39B from a retrograde approach.

Figs. 41A -41B, 42A-42B and 43 illustrate valve leaflet grasping devices which utilizes a pinching method.

Figs 44A-44D are schematic illustrations of an atrial-ventricular valve leaflet grasping device which utilizes a pinching method.

Figs 45A-45B are schematic illustrations of a grasping device which utilizes rollers in a pinching method.

Figs. 46A-46B are schematic illustrations of a grasping device which utilizes a pair of opposing coils in a pinching method.

Figs. 47A-D illustrate a pronged valve leaflet device which utilizes a pinching, partially penetrating or piercing method.

Fig. 48 illustrates a vacuum-assisted stabilization catheter for use in the methods described herein.

Fig. 49 illustrates an embodiment of a valve suturing device.

Figs. 49A-49C illustrate an additional embodiment of a valve suturing device.

Fig. 50 illustrates a further embodiment of a valve suturing device.

Fig. 51 illustrates use of the catheter for capturing and suturing opposed mitral valve leaflets.

Fig. 52 illustrates the mitral valve leaflets which have been secured as shown in Fig. 51.

Figs. 53 and 54 illustrate an alternative anchor which can be used with the suturing devices.

Figs. 55A-55B illustrate the use of an expansible anchor in fixation.

Figs. 56 and 57 illustrate yet another suturing device.

Fig. 58 illustrates use of the suturing device of Figs. 56 and 57 to place sutures between valve leaflets of the mitral valve.

Fig. 59 illustrates yet another embodiment of a suturing device.

Fig. 60 illustrates use of the device of Fig. 59 and suturing opposed mitral valve leaflets.

Figs. 61A and 61B illustrate a stapling device which can be used to staple opposed leaflets of an atrioventricular valve.

Figs. 62A-D are schematic illustrations of fixation devices.

Fig. 63 illustrates an alternative two part fixation stapling device.

Fig. 64 illustrates use of the stapling device of Fig. 63 for stapling opposed valve leaflets of a mitral valve.

Fig. 65A-65C are schematic illustrations of coiled fixation devices.

Fig. 66 illustrates use of a self-securing anchor for attaching opposed surfaces on the leaflets of the mitral valve.

Figs. 66A-66B are schematic illustrations of penetrating fixation devices.

Figs. 67 and 68 are schematic illustrations of penetrating fixation devices with barb-like distal ends.

Figs. 69A-C and 70A-B are schematic illustrations of clips used as fixation devices.

Figs. 71, and 72A-72B are schematic illustrations of clips involving the use of graspers in the fixation mechanism.

Figs. 73A-73C illustrate a three-jaw clip-applier.

Fig. 74 illustrates a clip which has been applied by the clip-applier of Figs. 73A-73C.

Fig. 75 illustrates a device for applying radiofrequency energy to shorten valve chordae.

Figs. 76, and 77A-77B illustrates devices used to plicate and shorten valve chordae.

Fig. 78 illustrates a first exemplary approach for placing an annuloplasty ring.

Figs. 79 and 80 illustrate a second exemplary approach for placing an annuloplasty ring.

Fig. 81 illustrates a method for placing an anchored filament about a mitral valve annulus that can be used to tighten the annulus.

Fig. 82 illustrates a method for placing multiple sutures about a mitral valve annulus, where the individual suture plicate and tighten the annulus.

Figs. 83-85 illustrate an embodiment of an atrial device for valve tissue modification.

Figs. 86, and 87A-87C illustrate an embodiment of an atrial-ventricular device for valve tissue modification.

Figs. 88-89, and Figs. 90A-90B illustrate an embodiment of a ventricular device for valve tissue modification.

Fig. 91 shows a cutaway representation of the left ventricle.

Figs.92A and 92B shows an annuloplasty device for positioning in a gutter of the left ventricle.

Fig. 93 shows a cutaway representation of the left ventricle with the annuloplasty device positioned in the gutter.

Fig. 94 is a cross-sectional view of the heart showing the mitral valve, valve leaflets, annulus, and coronary sinus.

DETAILED DESCRIPTION

I. CARDIAC PHYSIOLOGY

The left ventricle LV of a normal heart H in systole is illustrated in Fig. 1. The left ventricle LV is contracting and blood flows outwardly through the tricuspid (aortic) valve AV in the direction of the arrows. Back flow of blood or "regurgitation" through the mitral valve MV is prevented since the mitral valve is configured as a "check valve" which prevents back flow when pressure in the left ventricle is higher than that in the left atrium LA. The mitral valve MV comprises a pair of leaflets having free edges FE which meet evenly to close, as illustrated in Fig. 1. The opposite ends of the leaflets LF are attached to the surrounding heart structure along an annular region referred to as the annulus AN. The free edges FE of the leaflets LF are secured to the lower portions of the left ventricle LV through chordae tendineae CT (referred to hereinafter as the chordae) which include plurality of branching tendons secured over the lower surfaces of each of the valve leaflets LF. The chordae CT in turn, are attached to the papillary muscles PM which extend upwardly from the lower portions of the left ventricle and interventricular septum IVS.

Referring now to Figs. 2-4, a number of structural defects in the heart can cause mitral valve regurgitation. Ruptured chordae RCT, as shown in Fig. 2, can cause a valve leaflet LF2 to prolapse since inadequate tension is transmitted to the leaflet via the chordae. While the other leaflet LF1 maintains a normal profile, the two valve leaflets do not properly meet and leakage from the left ventricle LV into the left atrium LA will occur, as shown by the arrow.

Regurgitation also occurs in the patients suffering from cardiomyopathy where the heart is dilated and the increased size prevents the valve leaflets LF from meeting properly, as shown in Fig. 3. The enlargement of the heart causes the mitral annulus to become enlarged, making it impossible for the free edges FE to meet during systole. The free edges of the anterior and posterior leaflets normally meet along a line of coaptation C as shown in Fig. 3A, but a significant gap G can be left in patients suffering from cardiomyopathy, as shown in Fig. 3B.

Mitral valve regurgitation can also occur in patients who have suffered ischemic heart disease where the functioning of the papillary muscles PM is impaired, as illustrated in Fig. 4. As the left ventricle LV contracts during systole, the papillary muscles PM do not contract sufficiently to effect proper closure. The leaflets LF1 and LF2 then prolapse, as illustrated. Leakage again occurs from the left ventricle LV to the left atrium LA, as shown by the arrow.

II. INTERVENTIONAL APPROACHES

The described methods and devices treat cardiac valve regurgitation, particularly mitral valve regurgitation, by intervention at various locations. First, as shown in Fig. 5, the valve leaflets LF may be directly attached or coupled to each other by a structure S or other means. Typical structures include suture, staples, clips, pins, or other closure devices of a type commonly used in attaching opposed tissue surfaces. Alternatively, the opposed surfaces on the valve leaflets could be attached using adhesives, fusion energy, including radiofrequency current, laser energy, microwave, ultrasonic energy, or the like. A variety of specific techniques for valve leaflet attachment will be described hereinafter.

A second and often preferred interventional point will be in the chordae, as shown in Fig. 6. There, an attachment structure S is shown to couple individual chordae or tendons which are attached to each of the two leaflets LF. A variety of specific structures can be utilized, such as snares, staples, sutures, coils,

clips, snaps, rivets, adhesives, and the like. Opposed chordae will usually also be attached directly, optionally employing any of the same structures listed above. Alternatively, opposed chordae may be indirectly tied or coupled together by a structure which links or couples their movement, but which does not physically attach chordae from each of the valve leaflets directly together. In addition to attaching the chordae, chordal intervention can include shortening the chordae, e.g., by applying energy to shrink the collagen therein, or may utilize mechanical plication devices, such as clips, to physically shorten the chordae.

A third interventional point is the annulus AN (shown in FIG. 1) of the mitral valve AV. An annuloplasty device, such as a ring or a partial ring, can be positioned on the annulus to strengthen or re-shape the annulus. The atrial side of the annulus has a smooth, sloping surface around the circumference of the mitral valve. However, it can be difficult to secure an annuloplasty device to the smooth surface of the atrial side of the annulus. The ventricular side of the annulus has a concave, annular "gutter" around the valve. The gutter provides a location in which an annuloplasty device can be located and held while it is fastened to tissue. Thus, percutaneous annuloplasty could be more readily attainable by delivering an annuloplasty ring to the ventricular side rather than the atrial side of the valve, as described more fully below.

III. ACCESS TO THE MITRAL VALVE

Access to the mitral valve or other atrioventricular valve will preferably be accomplished through the patient's vasculature in a "percutaneous" manner. By "percutaneous" it is meant that a location of the vasculature remote from the heart is accessed through the skin, typically using a surgical cut down procedure or a minimally invasive procedure, such as using needle access through, for example, the Seldinger technique. The ability to percutaneously access the remote vasculature is well-known and described in the patent and medical literature. Depending on the point of vascular access, the approach to the mitral

valve may be "antegrade" and require entry into the left atrium by crossing the interatrial septum. Alternatively, approach to the mitral valve can be "retrograde" where the left ventricle is entered through the aortic valve. Once percutaneous access is achieved, the interventional tools and supporting catheter(s) will be advanced to the heart intravascularly where they may be positioned adjacent the target cardiac valve in a variety of manners, as described elsewhere herein. While the methods will preferably be percutaneous and intravascular, many of the tools described herein will, of course, also be useful for performing open surgical techniques where the heart is stopped and the heart valve accessed through the myocardial tissue. Many of the tools will also find use in minimally invasive procedures where access is achieved thorascopically and where the heart will usually be stopped but in some instances could remain beating.

A typical antegrade approach to the mitral valve is depicted in Figs. 7 and 8. The mitral valve MV may be accessed by an approach from the inferior vena cava IVC or superior vena cava SVC, through the right atrium RA, across the interatrial septum IAS and into the left atrium LA above the mitral valve MV. As shown in Fig. 7, a catheter 10 having a needle 12 may be advanced from the inferior vena cava IVC into the right atrium RA. Once the catheter 10 reaches the anterior side of the interatrial septum IAS, the needle 12 may be advanced so that it penetrates through the septum at the fossa ovalis FO or the foramen ovale into the left atrium LA. At this point, a guidewire may be exchanged for the needle 12 and the catheter 10 withdrawn.

As shown in Fig. 8, access through the interatrial septum IAS will usually be maintained by the placement of a guide catheter 14, typically over a guidewire 16 which has been placed as described above. The guide catheter 14 affords subsequent access to permit introduction of the interventional tool(s) which will be used for performing the valve or tissue modification, as described in more detail below.

The antegrade approach to the mitral valve, as just described, is advantageous in a number of respects. For example, the use of the antegrade approach will usually allow for more precise and effective centering and stabilization of the guide catheter and/or interventional tool. Precise positioning, of course, facilitates accuracy in the tissue modification, particularly affixation of the valve leaflets or chordae. The antegrade approach also reduces the risk of damaging the subvalvular apparatus during catheter and interventional tool introduction and manipulation. Additionally, the antegrade approach eliminates the risks associated with crossing the aortic valve. This is particularly relevant to patients with prosthetic aortic valves which cannot be crossed. When employing chordal fixation, the tools can be placed very close to the free edge of the leaflet since they will be removed in a direction away from the chordae which are being fixed. Additionally, an antegrade approach allows more direct access to the valve leaflets unimpeded by presence of the chordae.

A typical retrograde approach to the mitral valve is depicted in Fig. 9. Here the mitral valve MV may be accessed by an approach from the aortic arch AA, across the aortic valve AV, and into the left ventricle below the mitral valve MV. The aortic arch AA may be accessed through a conventional femoral artery access route, as well as through more direct approaches via the brachial artery, axillary artery, or a radial or carotid artery. Such access may be achieved with the use of a guidewire 42. Once in place, a guide catheter 40 may be tracked over the guidewire 42. The guide catheter 40 affords subsequent access to permit introduction of the interventional tool(s) which will be used for performing the valve or tissue modification, as described in more detail below.

In some instances, a retrograde arterial approach to the mitral valve will be preferred due to its advantages. Use of the retrograde approach will eliminate the need for a trans-septal puncture. The retrograde approach is also more commonly used by cardiologists and thus has the advantage of familiarity.

Additionally, the retrograde approach provides more direct access to the chordae.

The interventional tool(s) used for performing the valve or tissue modifications may be specifically designed for the approach or they may be interchangeable. For example, tools may be specifically designed for an antegrade or retrograde approach, or they may be designed to be used with either approach. In any case, tools may be used in any appropriate fashion to achieve a desired result. However, for the sake of clarity, a nomenclature has been developed to describe the common usage of such tools. Tools which perform the modification procedure while primarily residing primarily in the atrium are referred to as "atrial" tools. These utilize an antegrade approach. Tools which perform the modification procedure while primarily residing in the ventricle are referred to as "ventricular" tools, and likewise utilize a retrograde approach. Tools which cross over the valve to perform the modification procedure, residing in both the atrium and the ventricle, are referred to as "atrial-ventricular" tools, and may utilize either an antegrade or retrograde approach.

IV. ORIENTATION STEERING

Approaching the desired valve or tissue structure for effective treatment, as described above, requires proper orientation of the catheters, tools and devices used throughout the procedure. Such orientation may be accomplished by gross steering of the device to the desired location and then refined steering of the device components to achieve a desired result.

Gross steering may be accomplished by a number of methods. First, a steerable guidewire may be used to introduce a guide catheter, interventional tool and/or treatment device into the proper position. The guide catheter may be introduced, for example, using a surgical cut down or Seldinger access to the femoral artery in the patient's groin. After placing a guidewire, the guide catheter may be introduced over the guidewire to the desired position. Alternatively, a

shorter and differently shaped guide catheter could be introduced through the other routes described above.

Second, a guide catheter may be pre-shaped to provide a desired orientation relative to the mitral valve. For example, as shown in Figs. 9 and 10, guide catheter 40 may have a pre-shaped J-tip which is configured so that it turns toward the mitral valve MV after it is placed over the aortic arch AA and through the aortic valve AV. As shown in Fig. 9, the guide catheter 40 may be configured to extend down into the left ventricle LV and to evert so that the orientation of an interventional tool or catheter is more closely aligned with the axis of the mitral valve MV. The guide catheter 40 of Fig. 10 orients an interventional catheter (not shown) in a lateral direction relative to the access of the mitral valve MV. Each of the guide catheters 40 shown in Figs. 9 and 10 may find use under different circumstances. For example, the guide catheter 40 of Fig. 10 might be particularly suited for introducing tools which modify the chordae CT, while the catheter 40 of Fig. 9 may be more useful for engaging tools against the valve leaflets. As shown in Fig. 9, a guidewire 42 may be positioned from the tip of the guide catheter 40 directly through the opening of the mitral valve MV. Interventional tools can then be directed over the guidewire 42 to form the particular procedures described hereinafter. Likewise, the interventional tool itself may be pre-shaped to provide a desired orientation.

Third, the guidewire, guide catheter or interventional tool may be actively deflected, e.g., having push/pull wires which permit selective deflection of the distal end in 1, 2, 3, or 4 directions depending on the number of pull wires, having shape memory nitinol, or having balloons, wires, wire cages or similar mesh structures to direct the device away from a cardiac structure and therefore into a desired position, to name a few.

Either of the guide catheters 40 shown in Figs. 9 or 10 may be provided with steering capabilities. For example, two or more adjustment wires 46 may be provided at the distal tip of the guide catheter 40 as shown in Fig. 11. These

adjustment wires may be active or passive, and may be positioned within the valve commissures to enhance alignment of the guide catheter with the mitral valve MV. As shown in Figs. 12A and 12B, the adjustment wires 46 may be positioned in the medial commissure MVC and lateral commissure LVC, and the guide catheter 40 may thus be moved from a central location, as shown in Fig. 12A to a more medial position, as shown in Fig. 12B. The catheter could of course also be moved in the lateral direction (not shown). The ability to position the guide catheter will be of great benefit in performing the specific interventions and valve modifications described hereinafter. It will be appreciated that similar steering mechanisms could be provided on an interventional catheter introduced through the guide catheter, and in some instances it may be most desirable to provide the guidewire, the guide catheter, and the interventional catheter with steering and positioning capabilities.

Steering wires 50 on a guide catheter 40 may also be provided to engage opposed surfaces within the left ventricle LV, as shown in Fig. 13. By providing such a steering capability, the distal tip of the guide catheter 40 can be moved further downward from the mitral valve. Catheter 40 of Fig. 13 would be particularly useful in combination with an interventional catheter which itself has steering capabilities which engage portions of the mitral valve, such as the valve commissures as described above.

As shown in Fig. 14, the guidewire 52 may have laterally deflectable steering elements 54 which may be positioned in, for example, the valve commissures as described previously. This way, the guidewire 52 may be positioned toward the medial or lateral sides of the mitral valve MV, and an interventional catheter 56 introduced over the guidewire to a desired target structure within or surrounding the mitral valve MV. Providing such a steerable and positionable guidewire, it is particularly advantageous when it is desired to position the tip of an interventional catheter 56 at a region well below the opening of the mitral valve. That is, neither the guide catheter nor the interventional

catheter have to be advanced fully to the opening of the mitral valve, leaving them free to be positioned elsewhere.

In some instances, it will be desirable to introduce interventional tools sequentially or simultaneously from both the antegrade and retrograde directions. While it will be possible to separately introduce guiding catheters and guidewires by the approaches described above, in at least some instances it may be preferable to pass a single guidewire between the vena cava and the right atrium, crossing the interatrial septum as previously described. The guidewire may then pass in an antegrade direction through the aortic valve, through the ascending and descending aorta, and then percutaneously out of the vasculature at a location remote from the heart, such as the femoral artery.

Location of a single guidewire in this manner provides a continuous "rail" through the heart, allowing placement of separate devices in both an antegrade and retrograde direction. Additionally, any interaction or cooperation between the devices is facilitated since they will necessarily advance toward one another in an alignment which is controlled and assured by the guidewire, e.g., when fully advanced any two devices will necessarily meet. Thus, one device would extend inward from the venous side of the heart in an anterior antegrade direction to the mitral valve, and a second device would enter through the arterial side of the heart in a retrograde direction. The two devices would then be precisely located relative to each other as they approach and optionally meet at or near the mitral valve. In a particular example, a stabilizing catheter could be introduced in a retrograde direction to approach the chordae and underside of the mitral valve leaflets to provide for temporary stabilization and/or leaflet coaptation, as generally described above. A catheter carrying a fixation device could then be advanced in an antegrade direction to approach the valve leaflets from above. The second device could then be separately actuated to affix the valve leaflets once the proper temporary stabilization has been achieved with the first device.

Fourth, the guidewire, guide catheter or interventional tool may be positioned with the use of a floating balloon. This may be most useful for use with an antegrade approach. The distal balloon of a balloon tipped guidewire or balloon tipped floppy catheter may be inflated and floated antegrade through the mitral valve. If the heart is slowly beating, blood will be flowing from the left atrium, through the mitral valve to the left ventricle. A floating balloon may be carried along this flow trajectory, carrying the guidewire or catheter with it. The balloon may then be deflated and newly placed guidewire or catheter may be utilized as desired.

Fifth, a hollow guidewire, guide catheter or interventional or other tool may be positioned with the use of a rigid, pre-shaped mandrel or insertable member. As shown in Figs. 15A-D, the mandrel 600 may be comprised of wire, metal, plastic or any suitable material that may be formed to hold a desired shape 601, such as a bend or bump. The mandrel 600 may then be inserted into a lumen in a flexible structure 602 to be positioned. Such a structure may be a hollow guidewire, guide catheter, interventional tool or any other tool or component of a structure. As the shape 601 is advanced, the flexible structure 602 conforms to the shape 601 as it is passed through. This may be utilized to position a structure or component of a structure in a desired location for later steps in the procedure.

It may be appreciated that any of the devices, systems and methods used for gross steering may be also be applied to refined steering of the device or device components to achieve a desired result. In particular, it may be desired to independently or dependently manipulate components of the interventional tools throughout the procedure. Such steering may allow urging of the components relative to the leaflets, annulus, atrial wall or other specific cardiac structures. This may be achieved with any of the devices or methods described above.

V. ORIENTATION ASSESSMENT

Proper orientation of the systems and devices is necessary for performing the valve or tissue modification. Both the orientation of the devices and the components of the devices, in relation to cardiac structures and to each other, are of concern. Cardiac structures to which orientation is desired may include the atrial walls, interatrial septum, valve annulus, valve leaflets, valve commissures, valve chordae, papillary muscles and ventricle walls, to name a few. Assessment of the orientation of the components and devices may be achieved by a number of mechanisms and methodologies.

First, orientation may be assessed by tactile feedback. Introduction and manipulation of the devices and components may allow them to contact cardiac structures or other devices. Such contact may guide the devices into proper position and relevant orientation. For example, it may be possible to tactilely sense the force of the distal end of a guidewire, catheter or interventional tool against the leaflets, commissures, annulus, chordae, papillary muscles, ventricular walls, and/or atrial walls, to name a few. The force may be translated along its length to its proximal end to provide feedback to the physician or operator. Similarly, sensors may be used to achieve a similar result. Additionally, the catheter or tool may have a lumen to allow for pressure monitoring. This may provide feedback throughout the procedure which may indicate the presence and level of mitral regurgitation.

Second, orientation may be assessed by visualization of the devices and components themselves. The components or the overall system may be modified for enhanced echogenic and/or fluoroscopic visibility. Echogenicity of a material in a blood medium is dependent on the difference in acoustic impedance (product of velocity of sound and density of the medium through which the sound wave is traveling) between the material and blood. Therefore, a thin polymer coating on the components or the overall system may provide modulation of the acoustic impedance at the interface of the component and blood, thereby improving echovisibility. Likewise, microscopic air bubbles trapped on the

surface or embedded within the coating may also improve echovisibility. Similarly, fluoroscopic visibility may be improved with radiopaque coatings, radiopaque marker bands, or the like. Additionally, a lumen within the catheter or tool may be provided to inject radiopaque contrast solution to improve fluoroscopic visibility or surrounding tissues. In any case, such coatings, markings and fluids may provide visualization of the devices and components themselves or any structures or elements used throughout the treatment procedure. Similarly, angioscopic vision may be used to access the orientation throughout the procedure.

Third, one or more orientation elements may be used to assess orientation of the components and/or systems in relation to cardiac structures, specifically the target valve. Thus, orientation elements may be any structure or feature that provides information as to the orientation of the component, device or system described herein. The elements may be separate from or integral with any part of the system or device. They may be removably or fixedly mounted on the guidewire, guide catheter, interventional tool and/or other device. Likewise, the elements may be components or parts of components of the device which provide one or more additional functions in the tissue modification procedure, such as stabilization, grasping, coaptation, adjustment or fixation. Further the elements may be atrial, ventricular or atrial-ventricular devices such that they may or may not cross the valve in the orientation assessment process. In addition, such elements may be used to steer and/or orient the components and systems prior to or simultaneous with assessment.

Orientation elements may be in the form of propellers, wings, petals, arms, loops, and the like. One or more of these elements may be present, typically extending radially from a central shaft. When two elements are present, they are commonly placed 120 to 180 degrees apart around the central shaft; more than two elements are typically arranged in a radial pattern around the central shaft. In the preferred embodiments, the orientation elements are typically placed either

perpendicular to the line of coaptation or following the line of coaptation. This may provide the most useful reference, however many other placement orientations may be used.

Examples of orientation elements placed perpendicular to the line of coaptation are depicted in Figs. 16 and 17. Fig. 16 is a short axis view of the mitral valve MV with an orientation element 612 shown having a pair of orientation structures 613 arranged 180 degrees apart around a central shaft 614. The orientation element 612 is shown perpendicular to the line of coaptation C. Such positioning of the element 612 may indicate that the device is in its desired orientation, specific components are in a desired orientation, or devices or components may be oriented in relation to the positioned element which may be more visible than other parts of the device.

Fig. 17 is a long axis view of the mitral valve MV. Here, a guidewire 615 with a pair of orientation propellers 616 is shown inserted through the mitral valve MV via a retrograde approach. Visualization of the propellers 616 may allow repositioning of the guidewire 615 until the propellers are perpendicular to the line of coaptation C. At this point, a guide catheter, interventional or other tool may be tracked over the catheter in the desired orientation. Such tracking may be facilitated with the use of a keyed, notched, oval or similar lumen for guidance. Similarly, such orientation propellers 616 may be mounted on a guide catheter with a keyed lumen for guided insertion of interventional tools.

Examples of orientation elements placed along the line of coaptation are depicted in Figs. 18 and 19. Fig. 18 is a long axis view of an orientation element 620 inserted into the valve opening along the line of coaptation C. An end view shown in Fig. 19 illustrates the penetration of the element 620 through the valve opening and the valve leaflets LF sealing against the element 620. In addition, portions of the orientation element 620 may contact the commissures CM at each end of the valve opening for support and/or for reference. Using the position of the orientation element 620 as a reference, the location of a variety of cardiac

structures, particularly the valve leaflets LF, are known. In addition, if the position of specific components of the device are known in relation to the orientation elements 620, such relation may be used to infer the relation of those components to the cardiac structures. For example, if the orientation elements are known to be perpendicular to the graspers, positioning of the orientation elements in the manner described above would ensure that the graspers would be aligned perpendicular to the line of coaptation C or in a desirable location to grasp the valve leaflets LF.

In this example, the orientation element 620 is shown as an inflatable bladder coaxially attached to a distal central shaft 621. Such a bladder may be comprised of a compliant or noncompliant material, such as PET, PUR, Silicone, Chronoprene, or the like. The bladder material itself may be echo or fluorogenic, or it may be filled with an echo or fluorogenic liquid or suitable medium, such as carbon dioxide or agitated saline. In its inflated state, it is preferred that the bladder is wide or thick enough to so that the endview of the bladder is visible in a short axis view of the mitral valve, as shown in Fig. 19, and that the bladder is long or high enough so that the anterior and posterior leaflets may seal against the bladder in systole.

In addition, as shown in Fig. 20, the bladder 625 may be supported by a frame 626. The frame 626 may be comprised of any suitable material, such as nitinol, stainless steel, plastic or any combination thereof, of any consistent or variable flexibility, and any cross-sectional shape, such as round wire, hollow tube or flat ribbon. This material may be echo or fluorogenic or treated for such effects. In addition, the shape of the frame 626 may be of any suitable symmetrical or nonsymmetrical geometry, including but not limited to triangular, rectangular, circular, oblong, and single or multi-humped. A rectangular geometry is depicted in Fig. 20. In addition, the frame 626 may be expandable as shown in Figs. 21A-C. In the collapsed state, Fig. 21A, the bladder 625 and enclosed frame 626 may be inserted through a lumen in a guide catheter or

interventional tool. When appropriately positioned, the frame 626 may be gradually expanded, Fig. 21B, to a desired geometry, Fig. 21C. It may be appreciated that the orientation element may function without inflation of the bladder 625 or with just the frame 625 and no bladder.

Fourth, orientation may be assessed by visualization of flow patterns resulting from system or component position with respect to cardiac structures. As mentioned, the heart may be slowly beating throughout the tissue modification procedure. As the heart beats, blood may be flowing from the left atrium, through the mitral valve, to the left ventricle. Visualization of these flow patterns using Color Doppler Echocardiography may allow inferences as to how systems or components are positioned. For example, as shown in Figs 22A, if a thin planar structure 650 is inserted in the valve opening with its long axis perpendicular to the line of coaptation C, a higher level of regurgitation may result due to blood flow through the unsealed portions 651. If the structure 650 is inserted with its long axis along the line of coaptation C, as shown in Fig. 22B, a lower level of regurgitation may result due to more adequate sealing of the valve leaflets LF against the structure 650. Thus, such a structure 650 or similarly designed device may be used as an orientation element.

VI. STABILIZATION

Before a valve or tissue modification or intervention is performed, it will usually be desirable to temporarily stabilize the interventional tool in relation to the a cardiac structure. By "stabilization" it is meant that the interventional tool will be somehow coupled to a cardiac structure so that any existing relative motion between the tool and the structure is lessened. Cardiac structures which may be utilized for coupling include the atrial walls, interatrial septum, valve annulus, valve leaflets, valve commissures, valve chordae, papillary muscles and ventricle walls, to name a few. Such stabilization is performed in order to facilitate a subsequent intervention. For example, an access catheter may be

mechanically coupled to the valve or tissue surrounding the valve, such as the annulus or the chordae, and the interventional tool deployed from the catheter to perform a desired intervention, such as suturing, stapling, snaring, annuloplasty, RF tissue modification, or the like. The stabilization will usually be terminated after the particular valve modification is completed, but in some instances the stabilization could be terminated and redeployed multiple times at various points throughout the procedure.

The stabilization mechanisms may be separate from or integral with any part of the system or device. They may be removably or fixedly mounted on the guidewire, guide catheter, interventional tool and/or other device. Likewise, the elements may be components or parts of components of the device which provide one or more additional functions in the tissue modification procedure, such as steering, orientation assessment, grasping, coaptation, adjustment or fixation. Further the mechanisms may be atrial, ventricular or atrial-ventricular devices such that they may or may not cross the valve in the stabilization process. In particular, such mechanisms may be used to steer and/or orient the components and systems prior to or simultaneous with stabilization.

In the preferred embodiments, three general categories of stabilization mechanisms may be formed for descriptive purposes: 1) stabilization against the atrial septum, atrial walls or ventricle walls, 2) stabilization against the valve, and 3) stabilization against the chordae or papillary muscles. Stabilization against the atrial septum may be useful when approaching antegrade with atrial or atrial-ventricular devices. As previously described, an antegrade approach involves crossing from the right atrium RA to the left atrium LA by penetrating the interatrial septum IAS. This may be accomplished with a needle bearing catheter, which may then be exchanged for an introducer, guide catheter or similar catheter. Interventional tools may be introduced through this catheter for tissue modification treatment. To prevent movement of the catheter in an axial direction, a stabilization mechanism may be used to engage and lock the

catheter to the interatrial septum. A preferred embodiment is shown in Fig. 23, which depicts a catheter shaft 660 having a distal balloon 661 and a proximal balloon 662 inflated on opposite sides of the interarterial septum IAS. Inflation of the balloons 661, 662 against the septum couples the shaft 660 to the septum and stabilizes the system. It may be appreciated that a number of components, such as disks, cages, balls, mesh, or other structures, may be used in place of one or more of the balloons to achieve a similar result.

Stabilization against the atrial septum may also be achieved by forming an introducer or guide catheter which is rigid through the interatrial septum and left atrium. Typically, such introducers or guide catheters are flexible along their length to facilitate introduction through the tortuous paths of the vascular system. In an antegrade approach as described, the catheter may be inserted through the interatrial septum with its distal end suspended in the left atrium. In the case of a flexible catheter, movements at the septum may not be translated linearly to the catheter tip. Therefore, there may be relative movement between the distal end and the portion passing through the septum. This may be reduced by coupling the distal end to the portion passing through the septum. In a preferred embodiment, the catheter shaft between and including the distal end and the portion passing through the septum may be made rigid. Referring to Fig. 24, the catheter shaft 670 may be comprised of stacked elements 671. The elements 671 may be domed disks or collar segments with domed ends which are mechanically coupled by a structure 672. The structure 672 may connect the centers of the elements 671, as shown, in a flexible manner so that the shaft 670 may be shaped in any desired geometry suitable for use in the tissue modification treatment. Once a desired shape is formed, the structure 672 may be rigidified to hold the shape. Such rigidity may allow any movement of the interatrial septum to be translated to the distal end of the catheter shaft, thus coupling the catheter to the movements of the heart. This may improve stabilization of the devices and systems used in the tissue modification

treatment. It may be appreciated that a variably rigid shaft as described may be utilized for coupling to any cardiac feature and may be used with or as part of any device component or device in the procedure. Thus, the feature may be utilized to lock any device component, catheter or tool into place once it has been manipulated into a desired shape. This may be useful in a variety of situations in addition to those mentioned above.

Stabilization against the valve may be most useful when approaching antegrade with atrial or atrial-ventricular devices, however it may also be useful when approaching retrograde with ventricular or atrial-ventricular devices. When approaching antegrade, stabilization may be most easily achieved by coupling one or more components of the device to the atrial walls, valve annulus, valve leaflets, and/or valve commissures.

Coupling to the atrial walls may be accomplished by a number of stabilization mechanisms. In each embodiment, structures such as wires, ribbons, mesh, cages or balloons extend outwardly from the device, contacting and applying radial force to the atrial walls. Such contact may couple the movements of the atrium with the device for stabilization. A preferred embodiment is shown in Fig. 25. Here, flexible wires 680 bend out radially from the catheter shaft 681 with curved portions contacting the atrial walls AW. It may be appreciated that any number of wire patterns or means of extending from the shaft may be utilized, as mentioned above.

Coupling to the valve annulus may also be accomplished by a number of stabilization mechanisms, many of which include simultaneous coupling to other valve features, such as the leaflets and/or commissures. In preferred embodiments, such stabilization mechanisms may be comprised of loops, rings, wings, petals, arms, and the like. Coupling can be enhanced by varying surface friction and/or combining structures with vacuum. One or more of these mechanisms may be present, typically extending radially from a central shaft. When two elements are present, they are commonly placed 90 to 180 degrees,

preferably 120 to 180 degrees, apart around the central shaft. More than two elements are typically arranged in a radial pattern around the central shaft. Structure, size, angle and arrangement may be adjustable to fit individual patient anatomy.

Examples of such embodiments are shown in Figs. 26-29. Referring to Fig. 26, a guide catheter 14 may have deployable adjustment wires 20 to serve as a stabilization mechanism. The wires 20 are typically attached at one end to the distal tip of the guide catheter 14 and may be advanced at their other ends so that they selectively deploy from the guide catheter to engage the mitral valve MV. The adjustment wires 20 may act to stabilize or anchor the guide catheter relative to the mitral valve MV by coupling to the valve annulus, leaflets or commissures.

Similarly, the guide catheter 14 may have any number of stabilization elements, as illustrated in Figs. 27-29. As shown in Fig. 27, the stabilization elements may be comprised of a number of petals 22 arranged around the distal tip of the catheter 14. Similarly, the stabilization element may be a single large loop 25, as depicted in Fig. 28. Alternatively, the interventional catheter 30 may have a plurality of stabilizing arms 34 (Fig. 29) which both position and anchor the distal tip of the interventional catheter 30 relative to the valve annulus. Usually, at least three stabilizing arms will be utilized, with four being illustrated, however any number may be used. The stabilizing arms 34 may be pre-shaped, resilient metal rods (for example, formed from nitinol or other shape memory or superelastic alloy), ribbons, tubes, polymers or composites thereof that may be selectively extended from the tip of the interventional catheter 30 to engage the valve annulus. The interventional catheter 30 of Fig. 29 is shown with a separately extendable interventional tool 36 which performs the desired valve or tissue modification, as described in more detail below. Such stabilization elements may preferably engage the annulus located about the mitral valve MV

and apply forward pressure against the annulus to maintain contact and provide axial stabilization.

Stabilization may also be achieved by applying radial pressure to the commissures. As shown in Fig. 30, a pair of stabilization elements 32 may extend radially from a guide catheter 14 or interventional tool 30 to contact the commissures. The distance between the elements 32 may be equal to or slightly greater than the distance between the commissures to apply radial force against the commissures. The stabilization elements 32 may be comprised of any suitable material, such as nitinol, stainless steel, plastic or any combination thereof, of any consistent or variable flexibility, and any cross-sectional shape, such as round wire, flat ribbon or hollow tube. As shown in Figs. 31A-31D, the shape of the stabilization element may be of any suitable symmetrical or nonsymmetrical geometry, including but limited to triangular (Fig. 31A), rectangular (Fig. 31B), circular, oblong, double-humped (Fig. 31C) or single-humped (Fig. 31D). It may be appreciated that such stabilization mechanisms may also serve in orientation assessment, particularly as the frame 626 (Fig. 20) previously described. Thus, they may be echo or fluorogenic or treated for such effects. In addition, it may be appreciated that such stabilization elements may be passive, i.e., pre-sized and shaped to fit the patient anatomy so that they engage the valve annulus without adjustment, or may be active so that they can be used to steer the guide catheter as previously described.

A number of stabilization mechanisms apply both radial and axial pressure to the valve for stabilization. For example, the double-humped element, shown in Fig. 31C, has a superior hump 700 which may protrude into the left atrium, contacting the superior aspect of the annulus and possibly the left atrial wall, and an inferior hump 701 which may protrude into the left ventricle, contacting the inferior aspect of the annulus and possibly the left ventricle wall or chordal tissue. The superior hump 700 may apply a downward axial force on the annulus and the inferior hump 701 may apply an upward axial force. The waist 702 between

the humps may be dimensioned or adjustably sized to fit between the commissures and to apply a radial force on the commissures. Similarly, a single-humped element, shown in Fig. 31D, may provide similar stabilization without the added support from the protruding inferior hump. Additionally, this design may be easier to position in the mitral valve.

The last general category of stabilization mechanisms for descriptive purposes is stabilization against the chordae. Stabilization against the chordae may be most useful when approaching retrograde with ventricular or atrial-ventricular devices. Coupling to the chordae may be useful in stabilization for tissue modification to the valve, the chordae, the annulus or a combination of these. When modifying the valve, the contact with the valve structures (typically grasping of the valve leaflets) may still be necessary. However, when modifying the chordae, additional contact (such as grasping the chordae) may not be necessary since the stabilization methods may include this step. Therefore, stabilization against the chordae will be discussed in Section VIII Grasping.

VII. IMMOBILIZATION

Immobilization refers to substantially retarding or diminishing the motion of the cardiac structures or intermittently or temporarily stopping the cardiac cycle. This may be accomplished with a variety of methodologies. First, drugs may be injected to temporarily slow or stop the cardiac cycle. Such drugs may include but are not limited to esmolol, adenosine, isofluorane and transarrest mixture, with or without electrical pacing. Likewise, induced atrial fibrillation may interrupt the cardiac cycle.

Mechanical immobilization of the valve can be effected in a variety of ways. Most simply, valve action can be diminished or stopped by raising the pressure in the associated ventricle to a pressure above that in the atrium during diastole. For example, a suitable liquid can be infused into the ventricle to raise the intraventricular pressure, or the aortic valve could be temporarily

incapacitated allowing aortic regurgitation and raising the ventricular diastolic pressure. Alternatively, interventional tools and/or catheters carrying such tools may simply be mechanically stabilized against the valve, valve annulus, valve commissures, ventricular wall, atrial wall, generally as described above.

Mechanical valve immobilization will usually involve more interaction with the valve than simple stabilization. Immobilization will usually involve either capture and immobilization of either or both valve leaflets (or all three valve leaflets in the case of a tricuspid valve) or capture and immobilization of the chordae. For example, balloons or mesh cages may be used and placed under one or both leaflets to hold them partially closed. By temporarily immobilizing or adjusting the valve action, such as changing the point of coaptation, it is possible to see if a particular modification will be sufficient to treat the regurgitation. For example, by temporarily grasping the valve leaflets at a particular point and holding the leaflets together, it can be determined whether a permanent suturing, stapling, or other affixation at that point will achieve a sufficient reduction in regurgitation. When the heart is beating, valve regurgitation can be examined in real time via conventional imaging techniques, such as TEE. If the temporary valve modification appears sufficient, it can then be made permanent using any one of a variety of interventional techniques.

VII. GRASPING

Valve or tissue modifications or interventions most commonly require grasping a portion of the valve or tissue to be modified. Such grasping may be useful in adjusting tissues (such as coapting valve leaflets) for appropriate modification, checking the positioning of the tissues for improved biological function, and stabilizing or immobilizing the tissue for the modification procedure. As previously described, such grasping may also be useful to stabilize another tissue which will be modified in the procedure, such as the grasping the chordae to stabilize the valve for valve modification. Since the most common procedures

may involve valve modification or chordal modification, grasping of these cardiac structures will be discussed. However, it may be appreciated that described grasping devices, systems and methods may apply to any cardiac or other structure.

A. Chordal grasping

Grasping of the chordae may involve capturing and anchoring the chordae, as illustrated in Figs. 32-40. As shown in particular in Figs. 32A and 32B, a guide catheter 40 can deploy a first capture coil 60 and a second capture coil 62 through a pair of deployment catheters 64 and 66, respectively. The coils will be positioned while visualizing so that the first coil 60 captures chordae attached to a first valve leaflet LF and coil 62 captures chordae attached to a second valve leaflet LF. The capture coils will typically be elastic wires, preferably composed of a superelastic material such as nitinol, which are delivered through the deployment catheters in a straightened configuration. When they are advanced out of the deployment catheters, the capture coils will assume a helical or other configuration that can be advanced into and entangle the chordae.

The coils 60 and 62 may then be brought together laterally preferably coapt the leaflets LF together by advancing a retaining ring 68 which is secured at the distal end of a deployment wire 70, as illustrated in Fig. 32B. The leaflets are thus brought together and immobilized for a subsequent intervention. Alternatively, if immobilization via the coils 60 and 62 is sufficient in itself, it will be possible to make the deployment permanent. It is a particular advantage of the temporary immobilization that the valve action can be examined via the real time imaging techniques to see if regurgitation has been adequately addressed. If it hasn't, the coils can be redeployed or the relative positions of the two coils 60 and 62 can be changed until an adequate pair has been effected.

It will be appreciated that if a subsequent interventional step is required, it can be made from either an antegrade or retrograde approach. A variety of specific interventional techniques are described in detail hereinbelow.

An antegrade approach for deploying a single chordae snare 74 and optionally securing a suture loop about the captured chordae is illustrated in Figs. 33A and 33B. A guide catheter 14 deployed over the leaflets LF of the mitral valve MV may be deployed as described previously . A pair of deployment catheters 76 and 78 are advanced from the distal end of the guide catheter 14 and observed in real time via any of the imaging techniques described previously. The pre-shaped snare 74 is advanced out of the first deployment catheter 76 and is advanced through both of the chordae CT, as illustrated in Fig. 33A. A capture loop 80 is advanced from the second deployment catheter 78 and positioned so that it lies in the path of the pre-shaped snare 74 as it is advanced through the chordae CT. After a capture tip 82 passes through the capture loop 80, the loop can be tightened to secure to the capture tip 82 and draw the tip into the second deployment catheter 78. The capture tip 82 is attached to an end of a length of suture 84 (Fig. 33B) which runs back through a lumen in the snare 74. In this way, the suture may be pulled into the second deployment catheter 78, while the snare 74 is withdrawn back into the first deployment catheter 76, leaving only the suture in place grasping both the chordae. By then tying or otherwise securing the suture together into a permanent loop through the chordae, the coaptation of the valve leaflets LF can be modified in a desired way. As with the previous embodiments, a particular advantage of this approach is that the valve coaptation can first be viewed using the real time imaging capability to assure that valve regurgitation is adequately addressed before making the chordae capture permanent.

An alternative technique for deploying suture to capture chordae CT is illustrated in Fig. 34. First deployment catheter 90 (positioned through a guide catheter which is not shown) is positioned through the opening between valve

leaflets LF. A balloon 93 at the distal end of chordae snare 92 is extended through the chordae, as described previously. The balloon 93 is inflated and floated through the mitral valve during regurgitation. The balloon will pass through the previously deployed capture snare 95. Alternatively, the chordae snare 92 could be shaped so that it will encircle the chordae and then pass outwardly through the valve opening and into the previously deployed capture snare 95.

A chordae stabilization catheter 100 which is particularly suited for a retrograde approach is illustrated in Fig. 35. The catheter 100 includes a catheter body 102 having a pair of lumens 104 and 106 extending from a proximal end (not shown) to a distal end which is illustrated in Fig. 35A. The main lumen 104 extends fully to the distal tip of the catheter body 102 and a chordal snare 108 is slidably received in the lumen. The snare 108 has a loop pre-formed over its distal end so that, when extended from the catheter 100, it will assume the shape shown in Fig. 35. The loop has a diameter generally in the range from 3 mm to 20 mm and is shaped so that it will evert backwardly into a secondary loop formed by a capture snare 112. The capture snare 112 is disposed in the secondary lumen 106 and emerges from an opening 114 space proximally from the distal end of the catheter 100. The distal tip of the capture snare 112 is fixed at an anchor point 116 in the distal tip of the catheter body 102. Thus, by extending and retracting the capture snare 112, the capture loop can be moved between the position shown in full line and broken line.

Referring now to Figs. 36A and 36B, use of the catheter 100 for capturing and stabilizing chordae CT will be described. The catheter 100 is introduced in a retrograde direction (although antegrade would also be possible), typically through a guide catheter 40 as generally described above. Under direct (e.g., fluoroscopic) observation, the distal end of the catheter 100 will be guided to a position generally within the chordae CT, as illustrated in Fig. 36A. The chordae snare 108 will then be extended from the distal tip so that it passes through and

becomes entangled with the chordae CT attached to both of the leaflets LF. The distal tip of the chordal snare 108 will eventually pass through the loop defined by the capture snare 112, also as illustrated in Fig. 36A. The capture snare will then be tightened to hold the distal tip of the chordae snare 108, and the chordae snare then retracted so that the loop of the snare which passes through the chordae will be tightened, generally as shown in Fig. 36B. Generally, the catheter 100 will not be intended for permanently affixing the chordae CT. Instead, immobilization of the valve leaflets LF will be intended to facilitate a subsequent treatment step, as described hereinafter. Use of the retrograde approach for immobilizing the chordae CT will be particularly advantageous when used with antegrade interventions.

The catheter of Fig. 35 could, however, be modified to facilitate performance of retrograde interventions while the chordae are stabilized. As shown in Fig. 37, the catheter 120 includes a catheter body 122 which is generally the same as that shown for catheter 100 in Fig. 35 (with common components being given identical reference numbers), except that a third working lumen 124 is provided. The working lumen 124 can be used to deliver and position a wide variety of interventional tools for performing at least most of the specific interventions described elsewhere in this application. The catheter 120 will, of course, be particularly useful for performing interventions which rely on retrograde stabilization of the chordae CT of the type provided by the catheter. For example, the lumen 124 may be used to position an RF energy delivery tool for heating the chordae to cause shrinkage, as described in more detail below. Alternatively, the working lumen 124 could be used to position a chordae stabilization coil 130, generally as described in Figs. 39A and 39B. The coil is typically a helical filament having a secondary helical structure comprising, for example, three major loops. The coil may comprise an inner element composed of a shape memory material, such as nitinol, inserted into an outer coil 132 made of a radiopaque material, such as a platinum alloy. The shape

memory coil 134 is formed into a "stacked coil" configuration (with no space between adjacent windings of the coil) and then programmed so that it will assume the stacked coil configuration at a temperature slightly above body temperature. The coil assembly 130 is formed by heat treating the platinum 132 to a diameter D1 and length L1, as shown in Fig. 39A. The shape memory coil 134 is then stretched to a near linear configuration and inserted into the platinum coil 132, and the two are coupled at the end. Upon heating, the shape memory coil contracts back into its tightly stacked coil shape, compressing the platinum coil 132, and causing the entire assembly 130 to assume a smaller diameter D2 and length L2, as shown in Fig. 39B. The coil 130 may be delivered using a pusher catheter through the working lumen 124 so that it deploys within and entangles the chordae CT, as shown in Fig. 40. The pusher catheter (not shown) could be configured similarly to embolic coil delivery catheters, such as those described in U.S. Patent Nos. 5,226,911; 5,234,437; 5,250,071; 5,261,916; 5,312,415; 5,350,397; and 5,690,671, the full disclosures of which are incorporated herein by reference.

B. Valve leaflet grasping

Valve leaflet grasping may be accomplished using a number of methods, most commonly the following three: 1) pinching, 2) partially or fully penetrating or piercing, and 3) the use of suction or vacuum. Pinching involves grasping the surface or edge of the leaflet without penetrating the tissue. This may be accomplished by an antegrade or retrograde approach using atrial, ventricular or atrial-ventricular devices. It may be appreciated that although the following embodiments are examples which are described relative to a specific approach (antegrade or retrograde), each device or component may be used or adapted to be used in all approaches.

In preferred embodiments, depicted in Figs. 41-43, pinching of the valve leaflets LF can be achieved, for example, by using a grasping catheter

introduced in a retrograde direction to temporarily capture the free ends of the valve leaflets LF. It may be possible to use a simple two-jaw tool at the distal end of a catheter to capture both opposed leaflets. Such a two-jaw tool 710 is depicted in its open position in Fig. 41A. In this position, opposing jaws 711 may be positioned on opposite sides of the free ends of the valve leaflets LF. In its closed position, depicted in Fig. 41B, the leaflets may be drawn together and pinched to immobilize the valve. Although this may be adequate, it may be preferred to use a three-jaw capture tool as shown in Figs 42-43. The catheter 140 can be delivered through a guide catheter generally as described above. The catheter includes a tool 142 at its distal end. Tool 142, as best shown in Fig. 42B, includes a fixed center jaw 144 and a pair of pivotable outer jaws 146 and 148. The jaws 146 and 148 may be independently opened to a "capture" position as shown in broken line in Fig. 42B. Actuation of the jaws 146 and 148 may be achieved in a variety of conventional manners, including pull wires, push wires, inflatable balloons, heat memory alloy motors, and the like. By independently opening and closing the capture jaws 146 and 148 against the fixed jaw 144, the valve leaflets LF can be captured independently.

As shown in Fig. 42A, a first leaflet LF can first be captured. The catheter 140 can then be manipulated and positioned, typically under real time imaging, to capture the second leaflet LF, as shown in Fig. 43. It will be appreciated that independent capture of the leaflets greatly facilitates the procedure. Use of a single pair of capture jaws requires that the leaflets be captured at the instant when they are properly opposed. In the case of prolapsed valves, such an instance may never occur. Once captured and immobilized, as shown in Fig. 43, the valve leaflets can then be modified in any one of a variety of ways, as described elsewhere in the application.

Additional embodiments, depicted in Figs. 44-46, involve pinching of the valve leaflets LF by using a grasping catheter introduced in an antegrade direction to temporarily capture the surfaces or the free ends of the valve leaflets

LF. Referring to Figs. 44A-44D, the valve leaflets LF may be pinched between a superior loop 720 and an inferior loop 721. In a preferred embodiment, the grasper is comprised of a nitinol flat ribbon heat set in the shape of double loops 720, 721. The ribbon may be mounted on a series of three coaxial shafts, an interior shaft 725, a central shaft 726 and an exterior shaft 727. The distal end of the ribbon may be attached to the distal end 730 of the interior shaft 725, a midportion of the ribbon may be attached to the distal end 731 of the central shaft 726, and the proximal end of the ribbon may be attached to the distal end 732 of the exterior shaft 727. One or more ribbons may be mounted on the coaxial shafts; in this example, two ribbons are shown 180 degrees apart. When extended, as shown in Fig. 44A, the grasper may be pulled flat against the shafts 725, 726 ,727 for ease of insertion through a guide catheter or tool and into a desired position between the valve leaflets LF. When the central shaft 726 is retracted or the exterior shaft 727 advanced, as shown in Fig. 44B, the superior loops 720 may extend radially from the shafts. The superior loops 720 may rest on the superior surface of the valve leaflets LF in the atrium, as shown in Fig. 44D. In this position, the superior loops 720 may aid in orientation assessment, as the superior loops may be echo or fluorogenic and may be easily visible in relation to the cardiac structures or other devices or components. When positioned in a desired location, the interior shaft 725 may then be retracted, as shown in Fig. 44C, to extend the inferior loops 721 radially from the shafts. The inferior loops 721 may be in contact with the inferior surface of the valve leaflets LF in the ventricle. Thus, the valve leaflets LF may be pinched between the inferior loop 721 and superior loop 720. It may also be appreciated that the inferior loops 721 may be deployed prior to the superior loops 720.

Referring to Figs. 45A-45B, the valve leaflets LF may be pinched between a superior roller 750 and an inferior roller 751. As shown in Fig. 45A, the rollers 750, 751 may be mounted on a shaft 755 and connected by a pull actuation wire 756. The rollers 750, 751 may be serrated or surface treated in a directional

pattern to facilitate grasping of the valve leaflets LF. To grasp a leaflet LF, the rollers 750, 751 may be placed against the surface or free edge of the leaflet LF. Pulling of the actuation wire 756 may rotate the superior roller 750 and inferior roller 751 toward each other. This may draw the leaflet LF between the rollers 750, 751, as shown in Fig. 45B. Thus, the leaflets LF may be individually grasped for treatment.

Referring to Figs. 46A-46B, the valve leaflets LF may be pinched between a pair of flat coils 770. In a preferred embodiment, each coil 770 may be comprised of nitinol flat ribbon heat set in the shape of a coil. As shown in Fig. 46A, the coils 770 may be linked together with opposing curvature by a clip 772. Movement of the clip 772 along the coils 770 may uncurl the coils 770 to a straightened configuration. As shown in Fig. 46B, this may also be accomplished by a catheter shaft 773 placed over the coils 770. In the straightened position, the coils 770 may be inserted between the valve leaflets LF in an atrial-ventricular position so that the distal ends 775 of the coils 770 are in the ventricle. As the shaft 773 or clip 772 is retracted, the coils 770 may begin curling radially beneath the valve leaflets LF and upwardly so that the distal ends 775 of the coils 770 contact the inferior surface of the valve leaflets LF. Similarly, if the coils 770 continue curling, a portion of the flat ribbon proximal to the distal end 775 may contact the valve leaflet. In this manner, the leaflets may be grasped for treatment. Such a grasping device may also serve as a fixation device with the pair of coils 770 left in place, as will be described in a later portion of the application.

A valve or tissue structure may also be grasped by atraumatic partial or full penetration or piercing. This may be accomplished with a variety of grasping mechanisms. Preferred embodiments include one or more prongs extending from an interventional tool in an arrangement to grasp a specific structure. Specifically, three opposing prongs may extend from a grasping sheath with distal ends configured to pinch, partially penetrate or pierce. Such ends may be

pointed or may be soft, as in the case of rounded, urethane coated or solder coated ends. Referring to Fig. 47A, the opposing prongs 800 may be retracted into a grasping sheath 801 to hold the prongs 800 in a closed configuration. It may be preferred to orient the device to a desired position in this configuration. When the target tissue has been located, the prongs 800 may be extended to grasp the tissue structure, as shown in Fig. 47B. This may be accomplished by either extending the prongs 800 axially or retracting the grasping sheath 801. The target tissue may be pinched, partially penetrated or pierced with the prongs 800 in this configuration, or such action may be facilitated by closing or partially closing the prongs 800 as previously depicted in Fig. 47A. Alternatively, the prongs 800 may be attached to or integral with a prong-tipped tube 802, as shown in Fig. 47C. Such a design may be more conducive to the insertion of tools or fixation devices for further treatment steps, such as tissue modification. Tools or devices may be inserted through a lumen in the prong-tipped tube 802, depicted by arrows 804, for use at or near the grasping location. Similarly, tools or fixation devices may be inserted through a lumen in a hollow prong 806, as depicted in Fig. 47D. Here, one or more prongs 806 may be hollow, and the remaining prongs 808 may be comprised of solid wire or a suitable material. Tools or devices may be inserted through a lumen in the hollow prong 806, depicted by arrows 810, for use at or near the grasping location. Prongs, hollow or solid, may be made from stainless steel, NiTi, plastic or other suitable material. Additionally, they may be coated or coiled to enhance visibility. Likewise, the geometries of the prongs may be varied to facilitate grasping of the desired amount of tissue. And, the distal tip sharpness and surface finish can be varied to establish the amount, if any, of piercing.

In addition to directly engaging the valve leaflets to effect stabilization and/or immobilization with the grasper devices described above, the devices and methods may also employ a catheter or other tool having vacuum or suction applicators to temporarily capture the valve leaflets. As shown in Fig. 48, a

catheter 812 comprises a shaft having a pair of vacuum applicator rods 813 and 814. Usually, the vacuum applicator rods 813 and 814 will comprise separate shafts which may be axially translated relative to the main shaft of the catheter. Further optionally, the shafts could be articulated or otherwise manipulable so that they can be independently positioned relative to the valve leaflets or other tissue structures once the catheter 812 is in place. The vacuum applicators have one or more apertures to permit contact and adherence to tissue when the applicators are attached to external vacuum sources. Usually, the shaft will be placed across the valve, either in an antegrade or retrograde fashion, and the applicators positioned to grasp and manipulate the valve leaflets. Optionally, the catheter 812 may comprise additional stabilizing and/or steering wires of the type previously described. For example, a steering wire 815 (and optionally a second steering wire on the opposite side) may be provided for engaging against the valve commissures to permit positioning of the catheter with respect to the valve leaflets. The vacuum applicators would further be independently positionable to engage the valves in the desired fashion. Using this catheter, the leaflets can be grasped and the competency of the valve evaluated using the methods described previously. The valve adjustment can then be effected using any of the interventional approaches described herein. Further, it may be appreciated that in each embodiment, timing of grasping may be facilitated by the use of gating with the patient's EKG, pressure waves of the cardiac cycle, audio heart sounds, electronic pressure or contact sensors on the graspers.

VIII. COAPTATION, ADJUSTMENT AND EVALUATION

Once the valve leaflets, chordae or tissue structure is grasped by an interventional tool, the tissue may be manipulated to achieve a desired result, such as improvement in valve function. Such manipulation may occur during the grasping step, or it may require a separate step following grasping. In the case of leaflet modification, valve leaflets may be coapted or brought together and

held in a preferred apposition. The valve function may then be evaluated for indications of improved valve function, such as reduced regurgitation. If further improvement is desired, the valve leaflets may be additionally manipulated or adjusted. Adjustment should primarily occur in a superior/inferior (up/down) motion in order to bring the leaflets to a final positioning where regurgitation is minimized. During adjustment, one or both leaflets may be released and recaptured with new positioning. After the final evaluation, the valve leaflets may be fixated in the desired position by an appropriate fixation device. In the case of chordae shortening or other tissue modification, similar steps may be taken.

IX. TISSUE MODIFICATIONS

Repair of atrioventricular or other cardiac valves is effected by modifying the valve or a supporting tissue structure in some way to affect blood flow through the valve during a phase of the cardiac cycle, for example to permit blood flow through the valve during diastole when the associated ventricle is filling with blood but which inhibits or prevents blood regurgitation back through the valve during systole. A number of techniques for modifying the valve closure by capturing or grasping the chordae attached to each valve leaflet have been described above. These techniques are often used just for valve grasping and/or coaptation and adjustment prior to a separate valve modification step, but they may also be made permanent to provide the final valve modification. Other techniques for more directly modifying the leaflets or other supporting structures of the atrioventricular valves will be described in this section. These techniques may be utilized either with or without the valve grasping and/or coaptation and adjustment techniques described above. For purposes of simplicity, however, the following methods will generally be described without specifically illustrating such grasping, coapting and adjustment approaches, focusing primarily on the methods and devices involved with fixation. In addition, it may be appreciated that although the following embodiments are examples which are described

relative to a specific approach (antegrade or retrograde), each device or component may be used or adapted to be used in all approaches. Further, although devices and methods are described for fixating specific tissues, such as valve leaflets or chordae, such devices and methods may be used for any cardiovascular tissues and the like.

A. Fixation of Valve Leaflets

Suture can be delivered through the valve leaflets and then tied in a manner analogous to an open surgical procedure. In one embodiment, a suturing tool 200, shown in Fig. 49, may be positioned at the distal end of an interventional catheter. The interventional catheter will usually be advanced in an antegrade direction (i.e., from above the mitral valve), either directly through a guiding catheter or through a working lumen in a stabilization catheter. The tool 200 carries a length of suture 202 attached to a pair of needles 204 at either end thereof. The suture may be comprised of conventional suture material or of wire, typically stainless steel, nitinol or other material. The needles are held on a reciprocating shaft 206 disposed within a lumen of a retrieval sheath 208. The tool 200 can be positioned to capture the opposed free ends of the mitral valve leaflets LF, generally as shown in Fig. 49. The needles can then be advanced through the leaflets LF by drawing the shaft 206 toward the sheath 208 so that the needles 204 penetrate the leaflet and are captured in needle receptacles 210 formed in the sheath 208. The sheath can then be withdrawn. A knot can be tied in the suture, and the knot then advanced through the associated catheter to tighten over the valve leaflets. The tool 200 can carry two, three, four, or even more lengths of suture which may be simultaneously or sequentially introduced into the valve leaflets in order to permit multiple suture loops to be placed. The resulting tied suture loops will be similar to the "bow tie" sutures placed in open surgical procedures which have been described in the medical literature as described above.

The need to place and draw long lengths of suture through the valve leaflets can, however, be deleterious to the fragile leaflet structures. Thus, alternative needle and suture devices which rely on mechanical fasteners in relatively short suture lengths may be preferred. In one embodiment, a hollow suturing coil 1300, shown in Fig. 49A, may be positioned at or near the distal end of an interventional catheter. The suturing coil 1300 may be comprised of any material of sufficient rigidity to pierce and penetrate through valve leaflets LF, such as stainless steel, various shape memory or superelastic materials, metal alloys and various polymers, to name a few. The hollow suturing coil 1300 may contain a suture 1302 comprised of conventional suture material or of wire, typically stainless steel, nitinol or other material. The suture 1302 may be secured at the tip 1304 of the coil 1300 with a toggle rod 1305. After the valve leaflets LF have been grasped and coapted, the suturing coil 1300 may be advanced in a corkscrew fashion through the valve leaflets LF, as shown in Fig. 49A. Though such advancement is shown from above, advancement may be made from any direction through any number and configuration of valve leaflet layers. When advancing, the sharpened tip 1304 of the coil 1300 may pierce through the leaflets LF any number of times. It may be appreciated that such corkscrew piercing may be made through the middle portions of the leaflets such that a pierce is made at each half-rotation, or the piercings may be made along the edges of the leaflets such that a pierce is made at each full-rotation, to name a few.

Once the coil 1300 has advanced to a desired location, the toggle rod 1305 may be secured against a leaflet LF to hold the suture 1302 in place. At this point, the coil 1300 may be removed by retracting the coil 1300 in a reverse corkscrew fashion, as depicted in Fig. 49B, leaving the suture 1302 behind. Since the coil 1300 may be much larger in diameter than the thickness of the leaflets (to aid in placement), the suture 1302 may be loose-fitting and the valve leaflets LF insufficiently modified. The suture 1302 may then be tightened, as

shown in Fig. 49C, so that the suture 1302 holds the leaflets LF together in a desired configuration. This may be aided by the use of a soft-tipped catheter 1306 which may be advanced to contact the surfaces of the leaflets LF when tightening to prevent the leaflets LF from prolapsing. Once the suture 1302 is sufficiently tight, a restrictive collar 1308 may be deployed from the catheter 1306 or another device to secure and terminate the suture 1302. Such a restrictive collar 1308 may be comprised of any suitable material, such as heat-shrink tubing, nitinol shape-memory or superelastic coil or the like. Thus, this embodiment eliminates the need for needle passers and needle receivers providing a simplified method of valve leaflet fixation.

Alternatively, referring to Figs. 50 and 51, a short length of suture 220 may be positioned using a curved needle 222 which can be extended from the distal tip 224 of an interventional catheter 225. The needle 222 is formed from an elastic material, such as a shape memory alloy, and may be constrained in a generally straightened configuration within the catheter 224. When extended, as shown in Fig. 50, it assumes a curved shape so that it may be advanced through the atrioventricular or other cardiac valve leaflets LF, as shown in Fig. 51. A distal anchor 226 is secured to the distal end of the suture 220 while a slideable, locking anchor 228 is placed over a portion of the suture located proximally to the distal anchor 226 as shown in Fig. 50. The catheter 225 may be advanced to the valve leaflets LF in a retrograde approach, as shown in Fig. 51, using a guide catheter 40, as generally described above. The distal end 224 of the catheter 225 is positioned adjacent to the underside of a valve leaflet, and the needle 222 then advanced outwardly from the distal tip so that it passes through both valve leaflets.

In order to assure that the valve leaflets are in a proper orientation prior to needle advancement, the valve leaflets may be coapted and observed using any of the techniques described previously. After the needle has been advanced through the leaflets LF, a deployment sleeve 230 is advanced to release the

slideable anchoring catheter 228 from the needle and advance it toward an underside of the valve leaflet LF. As the anchor 228 approaches the valve leaflet, tension on the suture 220 will pull the distal anchor 226 from the needle. The deployment sleeve 230 can be advanced sufficiently to draw the two anchors 226 and 228 together on opposite sides of the valve leaflets, as seen in Fig. 52. The suture can then be tied off or, alternatively, locked in place using a mechanical lock 232. If the suture is comprised of a malleable wire, as previously described, the wire may be twisted together. In either case, the suture is then severed and the catheter 225 withdrawn.

The anchors 226 and 228 shown in Fig. 50 are generally oval shaped and have a length dimension which is greater than the width of the needle used to introduce them. Thus, when pulled laterally, they can seal against the opposed surfaces of the two valve leaflets. In some instances, however, it will be desirable to have anchors which are capable of expanding to a much larger dimension to assure that they do not pull through the relatively fragile tissue of the leaflets. An exemplary expansible anchor 240 is shown in its collapsed configuration within a needle 242 in Fig. 53 and its expanded configuration in Fig. 54. The anchor 240 is connected to a length of suture 244 and could be used with a similar slideable, expansible anchor (not shown) analogous to the non-expansible anchor 228 of Fig. 50.

Additional expansible anchors may be seen in Figs. 55A and 55B. In this embodiment, the anchor is comprised of an expanding randomly oriented wire coil. The coil is made from a shape memory nitinol wire that is annealed (heat set) in a straight configuration and then coiled. As shown in Fig. 55A, different sections 820, 821 of the coil may be processed to have different properties by varying the diameter and tension in the coil along its length. When the coil is heated to a specified level (T1), such as with RF energy, a designated portion 821 of the coil will become a randomly oriented mass of wire 824 with self-locking struts to prevent disentanglement. When the coil is heated to a different

specified level (T2), a different designated portion of the coil 825 will become randomly oriented. As each portion of the coil 824, 825 expands and changes shape, a full entanglement of the coils is allowed to occur, effectively compressing and fixing the two halves 824, 825 of each coil together. The coil may be introduced through the valve leaflets LF with the use of a shape memory, super elastic or heat/current activated needle introducer 826. Once the valve leaflets LF are pierced, an anchor 824 may be activated and deployed distally. The introducer 826 may then be retracted to the proximal side of the second leaflet LF2 and the second anchor (not shown) may be deployed in the same manner. The amount of tension between the anchors 824, 825 may be affected with the shape memory or super elastic properties of the expanding anchor. It may be appreciated that the heat activated expanding coil may alternatively take other forms, such as a wire mesh, for example. Additional expansible anchors may be in the form of inflatable chambers filled with a liquid that may optionally partially or fully solidify.

Yet another form of detachable anchor attached to a length of suture is illustrated in Figs. 56 and 57. Fig. 56 is a front view, while Fig. 57 is a side view of the same structure. A self-penetrating anchor 260 attached to a length of suture 262 is carried on a pair of rods 264. The rods are mounted within an open lumen of a deployment catheter 266. The anchor 260 can pivot on a detent structure 268 formed between the distal ends of the deployment rods 264. The anchor has a sharpened distal tip 270 which permits the anchor to be directly penetrated through the valve leaflet tissue when the rods are extended from the catheter 266.

Referring now to Fig. 57, the catheter 266 may be deployed over the leaflets LF of the mitral valve MV in an antegrade direction through a guide catheter 14 as generally described above. The catheter 266 can be used to deliver a pair of the anchors 260 sequentially. As shown in Fig. 58, a first anchor 260a has been deployed through a first leaflet and a second anchor 260b has

just been placed through the second leaflet. The anchors 260a and 260b are deployed by pushing them through the leaflet tissue while the sharpened tip 270 remains generally in a distal or forward direction. After passing through the tissue, the anchor 260a/260b can be turned, either by pulling back on the deployment rods 264 or by pulling backwardly on the suture 262. The two ends of suture 262 can then either be tied or fastened using a mechanical fastener in order to draw the opposed leaflets into proper apposition.

Referring now to Figs. 59 and 60, a deployment catheter 290 having a needle 280 with sharpened distal tip 282 can be used to place suture loops in individual valve leaflets. A needle 280 is carried on a pair of actuator rods 284 with a length of suture 286 attached to the needle. The needle 280 is first passed through the leaflet in a generally axial orientation with respect to the catheter 290. After passing through the leaflet from a guide catheter 14, as shown in Fig. 60, the needle is canted at an angle from 20° to 30° and passed back through the leaflet at a different position. A locking groove 288 on the needle is captured on a bar 292 in the distal end of the catheter 290. The needle 280 may thus be detached from the rods 284 to pull suture 286 in a loop back through the leaflet. This way, loops of suture may be placed successively through both leaflets LF of a mitral valve MV, as shown in Fig. 60. The suture loops may then be tied off, connected with fasteners, fused together using RF, microwave or ultrasound energy, or otherwise secured to close the valves together in a desired apposition.

In addition to sutures and suture-based devices, as just described, opposed points on the valve leaflets and/or chordae can be attached with a variety of staples and tissue-penetrating fasteners. The staples and other fasteners can be delivered through guide catheters, generally as described above, and may be positioned during or after valve grasping, coaptation and adjustment, also as described above.

Referring now to Figs. 61A and 61B, staple applying catheter 300 is schematically illustrated. Typically, the leaflets LF of a mitral or other atrioventricular valve will first be accessed by any of the techniques described above. The catheter 300 will then be introduced in a retrograde fashion, for example, as illustrated previously. A staple 302 is held in an open position at the distal tip of the catheter 300 and has a generally W-shaped profile with two recesses for receiving each of the leaflets LF, as shown in Fig. 61A. After proper positioning is confirmed visually, the staple 302 may be closed over the leaflets so that the tips penetrate opposed points on each leaflet by pulling on an actuator cord 304, as shown in Fig. 61B. The actuator cord can then be detached and the catheter 300 withdrawn, leaving the staple 302 in place to hold the leaflets together. Optionally, additional clips can be placed in a like manner to further strengthen the affixation of the leaflets. As described, the clip is a malleable clip which undergoes plastic deformation for emplacement. Alternatively, the clip could be formed of an elastic material, such as a shape memory alloy, and held in its open position as shown in Fig. 61A. The clip could then be placed by releasing it to return to its memory (closed) configuration, as shown in Fig. 61B. Other actuation mechanisms could also be used, such as the use of heat to induce a shape change in a heat memory alloy staple.

In addition, two part snaps, rivets and staples may be used to hold leaflets in place by locking together. This may be achieved by a number of device designs. Preferred embodiments involve two disks 850, pledgets, or the like, placed on opposite sides of tissues or leaflets LF to be bound together, as shown in Fig. 62A. Typically a shaft 852, pin or needle may pierce the leaflets LF and connect the two disks 850. The disks 850 may then be snapped or joined together by interlocking one or both disks 850 to the shaft 852 and/or portions of the shaft 852 to each other. Such a fixation device may be introduced through a lumen of a specialized catheter 854, introducer or component of an interventional tool, as shown in Fig. 62B. The disks 850 may be solid and/or rigid requiring

placement on each side of the tissue, or the disks 850 may be flexible, collapsible and/or inflatable such that they may be inserted through the tissue for placement on the other side of the tissue. Preferred embodiments also involve two disks 855, pledgets, or the like, which are placed between tissues or leaflets LF to be bound together, as shown in Fig. 62C. Here, the disks 855 have penetrating prongs 856 at each end to pierce and grasp tissue. When the disks 855 are snapped or joined together by interlocking one or both disks 855 to a shaft 858, shown in Fig. 62D, and/or portions of the shaft 858 to each other, the leaflets LF may be bound together.

An additional embodiment of a two part rivet-like stapling mechanism is illustrated in Fig. 63. A stapling mechanism 322 at the distal end of a catheter 320 comprises a first jaw 324 which carries a fastener 326 and a second jaw 328 which carries a retaining ring 330. The fastener has a collapsible cone 332 at its distal end so that it may be forced into an aperture 334 in the retaining ring 330. The jaws 324 and 328 are pivotally mounted within the distal end 340 of the catheter so that they may be opened and closed to grasp the free ends of the valve leaflets therebetween. The closing of the jaws 324 and 328, however, does not lock the fastener 326 into the retaining ring 330. Thus, the valve leaflets can be temporarily grasped and the improvement in valve regurgitation visually assessed. If the improvement is sufficient, the fastener 332 can be driven into the tissue and locked in the retaining ring 330. If the improvement is not sufficient, the jaws can be repositioned on the valve leaflets one or more additional times until an adequate or optimized repositioning of the leaflets is obtained. The fastener 332 can be driven into the retaining ring in a variety of ways. In the illustrated embodiment, a cam device 342 is slidably mounted behind an inclined surface 344 on the rear of the fastener 326. By drawing the cam actuator 342 downwardly using draw cord 348, the rivet can be driven through the valve leaflets and into the retaining ring 330, as illustrated in Fig. 64.

In addition to rivets, snaps, pins and the like, coils may be used in a similar manner to fix valve leaflets in a desirable arrangement, as shown in Fig. 65A. Coils 900 may be comprised of a superelastic material and pre-shaped in a coil configuration for engagement with the leaflets. The coil 900 may be advanced from an introducer sheath 902 to deploy the coil 900 in an orientation that will approximate the leaflets in compression. Alternatively, the coil 900 may be comprised of a heat or current activated shape memory material As depicted in Fig. 65B, the coil 900 may be straightened in its initial configuration for ease of piercing and advancing through the leaflets LF. When positioned, the material may be activated by heat or current to assume a shape memory coil configuration corresponding with Fig. 65A. Again, the coils may be oriented to approximate the leaflets in compression. To achieve maximum leaflet compression at the coaptation points, a super elastic or shape memory coil 900 may be delivered in a manner that places the coil in an inverted orientation across the leaflets, as illustrated in Fig. 65C. This may be accomplished with the use of a specialized delivery system 904. When released from the delivery system 904, the distal end 905 of the coil produces a compressive force as the coil attempts to achieve a non-inverted orientation.

As a further alternative, a cinch-type fastener 360 may be positioned in a loop through opposed valve leaflets LF, as shown in Fig. 66. The fastener 360 could be advanced from either a retrograde or antegrade direction, but the antegrade direction is illustrated for convenience. A positioning catheter 362 can be introduced through a guide catheter 14 which has been previously positioned by any of the techniques described above. After advancing the cinch-type fastener 360 through the leaflets, for example by pushing a pre-shaped fastener 360 through the leaflets so that it returns to the distal tip of the placement catheter 360, a fastening collar 364 may then be advanced to tighten the fastener loop 360 until the leaflets are positioned in a desired fashion. Alternatively, the fastener 360 may be twisted to constrict the open loop. Typically, the fastener

360 has chevrons or other one-way surface features so that the locking column may be advanced and will remain in place without loosening over time, or in the case of twisting, untwisting over time. The fastener 360 is then released and, if desired, additional fasteners positioned in a like manner. The fastening collar 364 may alternatively be used to secure the sutures shown previously in Fig. 49. The collar 364 may be crimped onto the sutures 202 or locked in place by the use of a combination of one-way surface features on the collar 364 and sutures 202.

Further, a variety of penetrating and non-penetrating clips, barbs, grappling hooks, and the like, may be used to fasten valve leaflets in a desired configuration. As previously described as a means to grasp the free ends of the valve leaflets in a pinching manner, a pair of flat coils may also be used as a fixation device. As previously shown and described in relation to Fig. 46A, the coils 770 may be linked together with opposing curvature by a clip 772. When inserted as shown in Fig. 46B, the coils 770 may be permanently joined in this orientation and may remain as a permanent implant. Alternatively, the coils 910 may pierce the leaflets LF to hold them in place as shown in Figs. 66A and 66B. During placement, the coil 910 may be inserted through a delivery catheter 911 in a straight configuration and pierce the leaflets LF in this form, allowing the free distal end 912 of the coil 910 to curl after it has penetrated the leaflets LF, as shown in Fig. 66A. The proximal end may then curl after it disengages from the delivery catheter 911 to remain as an implant as shown in Fig. 66B.

Likewise, a variety of barb-like structures may be used in a similar fashion to fasten valve leaflets in a desired configuration. Referring to Fig. 67, a shaft 920 with one or several curved barb-like distal ends 922 may be positioned so that the distal ends partially or fully penetrate each leaflet LF to be fixed. The shaft 920 may be a shape memory or super elastic wire. By activating the shaft 920 with heat or current, in the case of a shape memory material, or allowing the shaft 920 to assume its pre-configured shape, in the case of a super elastic

material, several barbs 922 may be approximated to coapt the leaflets in the desired position. On the other hand, several discontinuous barbs 922 may be tensioned and coapted using a crimping or coupling and trimming system. Similarly, as shown in Fig. 68, a shaft 924 with expanding barb-like distal ends 926 may be positioned so that the distal ends 926 penetrate each leaflet LF to be fixed. Here, however, the distal ends 926 may be comprised of one or more struts 927 which expand to further prevent retraction of the shaft 924. Such expansion may be achieved by activation of the shaft 924 with heat or current or allowing the device to assume its pre-configured shape. In addition to end 926 expansion, the shaft 924 may be approximated to coapt the leaflets or several discontinuous shafts may be tensioned and coapted using a crimping or coupling and trimming system.

In addition to fixation, clips may be used to draw leaflets together in a suitable coaptation configuration. While temporarily holding two or more leaflets in a desired configuration, such as with grasping tools, a clip may be deployed to maintain the desired position or to further manipulate the leaflets. For example, a clip 940 may be mounted on a delivery catheter or interventional tool 942, as shown in Fig. 69A. It may then be positioned in a desired location to hold the leaflets LF, as shown in Fig. 69B. In the deployed and activated state, depicted in Fig. 69C, the clip 940 may tend to pinch inwardly, pulling the leaflets together, as indicated by arrows 944. This may be achieved by activation of super elastic or shape memory material. Alternatively, referring to Figs. 70A and 70B, the clip 945 may pinch inwardly, indicated by arrows 944, by manual crimping of the spine 946 or interlocking of the piercing legs 948. When positioned appropriately between the valve leaflets LF, as shown in Fig. 70B, the leaflets may be drawn together by crimping the spine 946 of the clip 945 with the use of a removable actuator 950. As the actuator 950 passes over the spine 946, the spine 946 may be plastically deformed to a new configuration. Or, as the actuator 950 passes over the spine 946, the proximal ends of the piercing legs 948 may become

interlocked. In either case, inward movement of the clip 945 may be controlled by passing the actuator 950 only over portions of the spine 946 in which such pinching is desired. Therefore, a single clip may provide variable inward forces.

Inward forces may also be applied by components of an interventional tool, such as a by graspers. Graspers, as previously described, are devices which grasp and hold tissues (such as coapting valve leaflets) for appropriate modification, such as fixation. Thus, graspers are most likely in place while a fixation device is deployed and positioned. Referring to Fig. 71, an embodiment of graspers 960 is shown holding the leaflets LF on opposite sides of a deployed clip 962. Inward force may be applied to the clip 962 by moving or applying force to the graspers 960 in an inward direction, as depicted by arrows. In a further embodiment, the graspers may serve as a grasping device and as an implantable fixation device. Referring to Fig. 72A, an embodiment of graspers 960 is shown coapting and holding the leaflets LF together. The graspers 960 may then be joined by a coupling device 964 and detached for implantation, as shown in Fig. 72B.

Because of the fragility of the tissue in the valve leaflets, it will sometimes be preferred to utilize methods or devices which do not completely pierce or penetrate the tissue. For example, leaflets may be fused together in a desired coaptation position by applying laser, RF, microwave or ultrasonic energy at specified coaptation points. In addition or alternatively, external clips which are partially penetrating or non-penetrating may be used. A variety of deformable and elastic clips can be utilized, and clips will usually be deployed in a retrograde fashion so that an opening in the clip can be placed over the undersides of the adjacent valve leaflets.

A preferred clip-applying catheter 380 in is depicted in Figs. 73A, 73B, and 73C. The catheter 380 has a three-jaw clip-applying device 382 at its distal end. The three-jaw structure allows the clip-applier to be used as a three-jaw grasping device before final deployment of the clip. Such grasping has been described

earlier with reference to Figs. 42A, 42B, and 43 above. A center jaw 384 of the device has a tubular structure and allows the catheter to be introduced over a guidewire 386, where the guidewire may be placed through the atrioventricular valve prior to catheter positioning. A clip 388 has a V-shaped structure and is normally closed so that a force is required to open the distal ends of the clip. Jaws 390 and 392 hold the clip and can open the clip by selectively opening either jaw, with jaw 392 shown in open in broken line in Fig. 73A. Thus, jaw 392 may be opened first to capture a free end of a first valve leaflet. With the catheter 380 thus attached to just the first valve leaflet, the catheter can be repositioned so that the other jaw 390 can be opened and used to capture the second valve leaflet. After the valve leaflets are captured and held in a proper orientation, valve improvement can be confirmed by visual observation. If improvement is sufficient, the clip can be detached from the catheter and left in place, as shown in Fig. 74.

B. Shortening of the Chordae

In addition to suturing, fastening, and otherwise physically attaching portions of the valve leaflets and/or chordae together, valve leaflet closure can be improved by shrinking portions of either or both of the chordae attached to the two valve leaflets. An exemplary catheter 400 having an energy-applying coil 402 at its distal end is shown in Fig. 75. Such energy may be in the form of radiofrequency (RF), microwave, ultrasound, laser, heat or current. The catheter 400 may be deployed in either an antegrade or retrograde direction, with retrograde generally being preferred to facilitate access to the chordae. One or more chordae CT are captured within the coil and RF energy, for example, applied from a conventional power supply. Application of the RF energy to the chordae, which are composed of collagen and other normal tissue constituents, over a length L will cause shrinkage of the tissue to a length which is shorter than the original length L. Similarly, such application of energy to the chordae may

also be achieved with the use of an energy applying chordal snare or similar device. By applying such shortening of the chordae, valve conditions, such as prolapsed valves can be effectively treated.

In addition to the use of energy for shortening chordae, the chordae can be plicated using mechanical plication devices 420, as illustrated in Fig. 76. Each of the devices 420 comprise a cap piece 422 and a receptacle 424. A receptacle has a channel 426 which receives a pin 428 on the cap piece 422. There is sufficient clearance between the pin 428 and channel 426 so that a portion of the chordae CT can be captured and folded therein by placing the cap into the receptacle. Each plication device 420 will thus shorten a portion of the chordae by a predetermined amount. Multiple devices can be used to achieve a desired overall shortening of the chordae. The devices can be placed using jaw-type devices and shortening can be visually observed by any of the techniques described above. Alternatively, chordae may be mechanically plicated with the use of suture loops. Referring to Fig. 77A, a suture 980 may penetrate the chordae CT at a first location 982 and then penetrate the chordae CT again at a second location 984 forming a loop. By pulling closed the loop, as shown in Fig. 77B, the effective length of the chordae CT is reduced. The suture loop may then be fixed and trimmed for implantation. This may be repeated along a chordae to form multiple individual or continuous loops, and/or it may be repeated on along more than one chordae. Similarly, such plication may also be achieved with the use of a shape memory or super elastic wire coil which may penetrate a chordae at one or more points and draw the tissue together upon activation.

C. Annuloplasty

The intravascular approaches described herein can also be used to place annuloplasty devices, such as supporting rings and other devices, around the atrioventricular valve annulus, including the mitral valve annulus AN (shown in

Figure 1). Such annuloplasty devices can provide support which is analogous to that provided by annuloplasty rings implanted in open surgical procedures.

As mentioned, annuloplasty device can be positioned on either the atrial side or the ventricular side of the annulus. An advantage to positioning the annuloplasty device on the ventricular side of the annulus is that the device can be positioned within an annular gutter G that is located immediately adjacent the ventricular side of the mitral valve MV. The gutter G is shown in the cutaway representation of the left ventricle LV in Fig. 91. As mentioned, the gutter G has a concave shape, which provides a geometrically-supportive location in which the annuloplasty device can be securely nested during and after deployment of the device. The rounded, concave shape of the gutter G provides an increased amount of contact area between the wall of the left ventricle and an annuloplasty device positioned in the gutter.

The annuloplasty device can have a variety of configurations. For example, with reference to Figs. 92A and 92B, the annuloplasty device 1090 can be shaped as a ring (Figure 92A) or as a partial ring (Figure 92B). The annuloplasty device 1090 can be equipped with any of a variety of securing or retaining structures for securing the device to the heart, including hooks, barbs, prongs, adhesive fasteners, bendable legs, etc. In addition, secondary attachment devices or materials can be coupled to the annuloplasty device 1090, such as, for example, staples or adhesive, for permanently or temporarily securing the device to the annulus.

Fig. 78 shows another exemplary annuloplasty device comprised of an annuloplasty ring 500. The annuloplasty ring 500 includes an outer ring having radially-extending spokes 504, which can be used to open the outer ring. The annuloplasty ring can be deployed using a catheter 502 positioned through a guide catheter 14, as described more fully below. The ring can be secured in place using sutures, staples, tissue adhesives, or other conventional techniques. The catheter 502 may then be removed, together with the deployment spokes

504, leaving the ring permanently in place. One or more of the spokes can be attached to one or more clips that coapt the valve flaps. The spokes can be stiff or the spokes can be sutures or other flexible material to allow free or limited movement of the clips. Alternatively, rigid or flexible members in the form of sutures or pins/posts could extend upwardly from the annuloplasty device and penetrate through the annulus tissue to the left atrium where members fasten to the atrial side of the clip in tension. This could help to anchor the annuloplasty device in place and could partially or totally immobilize the clip, should that be desirable.

Magnets can also be used to secure the annuloplasty device 1090 to the heart. This is described in more detail with reference to Fig. 93, which shows the annuloplasty device positioned in the gutter G. A pair of magnets 9310a and 9310b sandwich at least a portion of the annuloplasty device therebetween. The magnet 9310a is located on a ventricular side of the mitral valve and the magnet 9310b is located on the atrial side of the mitral valve. The magnets are of opposite polarity such that they exert an attractive force on one another to force the device against the wall of the gutter G and retain the annuloplasty device in the gutter G. Alternately, the magnet 9310a can be replaced with magnetic material that is integrally formed within the annuloplasty device. The atrial magnet 9310b can be left in place permanently or it can be removed once annuloplasty device is permanently secured either through fixation devices of through tissue growth.

In an exemplary embodiment, the annuloplasty device is configured to be-reshaped after placement in the annulus. For example, the annuloplasty device can be malleable such that it can be reformed into a desired shape after placement of the device by using an endovascular grasping/shaping tool. In another embodiment, a pull wire spans the circumference of the device. The pull wire has a grasping means, such as a loop, handle, snare, etc. After the annuloplasty device has been deployed, the end of the pull wire is grasped and

pulled by a catheter so as to cause the wire to constrict the device into a smaller diameter or to re-shape the device in a predetermined manner.

The pull wire can alternatively extend from the annuloplasty device to an extra-cardiac location, either in the chest cavity or in a peripheral vessel for later access. The pull wire can be left in a subcutaneous location like a pacing lead to facilitate easy access. The pull wire and/or the annuloplasty device can be coated with agents to prevent endothelialization, tissue encapsulation, and infection.

In another approach, the annuloplasty device is formed at least partially of a thermal shape memory material that changes shape upon heating. A source of heat, such as an electrical lead through which current could be delivered, can be coupled to the annuloplasty device at a desired time to cause the device to change shape. Alternatively, the annuloplasty device could have a mechanism that is remotely controllable (from outside the body) so that it can be transitioned to the desired shape at any time during or after the procedure without further intervention. For example, the device could have magnetic components to allow the shape to be controlled via MRI steering technology. Other remotely controllable mechanisms are also possible.

In another approach of a re-shapeable annuloplasty device, the device has one or more articulating joints with one-way locking or ratchet mechanisms in each joint that allow the device to be shaped (e.g. by pulling a wire attached to one end) from straight into a curved or bent shape. The annuloplasty device can then be locked into the re-shaped configuration with any desired degree of curvature or angle.

The annuloplasty device can be resiliently flexible such that it can be compressed into a state of reduced size that would fit through the lumen of a guide or delivery catheter. In the reduced-size state, the annuloplasty device can comprise a flattened ring in a straightened configuration. When released from

the guide catheter, the annuloplasty device resiliently returns to a predetermined shape, such as the ring or partial ring shown in Figs. 92A and 92B. Thus, an elastic annuloplasty ring can be delivered through the guide catheter in a collapsed fashion, deployed to open over the annulus, and then stitched or stapled in place using appropriate catheters.

Rather than being comprised of a single ring or partial ring structure, the annuloplasty device can comprise of a plurality of structures that collectively re-shape the annulus when positioned therein. For example, a plurality of attachment members, such as staples or clips, can be positioned in an annular formation around the entire circumference of the annulus or along a portion of the annulus. Each attachment member is attached to the annulus in such a manner that it re-shapes a local portion of the tissue. The plurality of attachment members collectively re-shape a global area of the annulus.

The plurality of anchors approach is shown in Fig. 81, which shows a plurality of anchors comprised of as staples 540 about the annulus of the mitral valve, such as in the gutter described above. A suture 542 or other filament can then be placed through the anchors 540 and tightened in a "purse string" fashion. The suture filament can then be tied off to maintain the desired tightening and enforcement of the valve annulus.

As yet a further alternative, the valve annulus can be plicated by positioning a plurality of staples about the annulus, as shown in Fig. 82. Here, each staple 560 plicates or shortens a small peripheral segment of the annulus. A staple applying catheter 562 may have the same general structures described above in connection with Figs. 61A and 61B.

In an embodiment, a period of time elapses after placement of the annuloplasty device in the annulus. The annuloplasty device is then re-shaped after passage of the period of time. During the time period, the tissue around the annulus forms scar tissue where the annuloplasty device has been attached. In

this regard, the annuloplasty device can be covered with a suitable material, such as Dacron, that promotes tissue healing and growth. The scar tissue strengthens the attachment between the tissue and the annuloplasty device and reduces the likelihood of injury to the tissue or detachment from the tissue during reshaping. The amount of the time period can vary. In one embodiment, the annuloplasty device is deployed in the annulus and the annuloplasty device is re-shaped after a time period of four to twenty four weeks has elapsed.

The annuloplasty device can be delivered to the annulus in a variety of manners and using various devices. The annuloplasty device can be delivered using an antegrade approach or a retrograde approach. As discussed above with reference to Fig. 9, in the retrograde approach, the annuloplasty device is introduced by deploying a delivery device through distal arterial vasculature and over the aortic arch and into the left ventricle through the aortic valve. As discussed above, a guidewire 42 can be used to provide initial access to the left ventricle. A guide catheter 40 is then tracked over the guidewire 42 to the left ventricle.

An interior lumen of the guide catheter 40 provides subsequent access to the left ventricle for a delivery catheter that holds the annuloplasty device at its tip. When entering through the left ventricle, the delivery catheter may be required to curve or turn such that it approaches the gutter of the mitral valve annulus from below. In this regard, the delivery catheter may have a predetermined shape that facilitates such an approach. The delivery catheter can also have a deflectable distal tip that can be deflected (such as via a pull wire) so that the distal tip angles outwardly and upwardly toward the gutter region of the annulus. The delivery catheter then deploys the annuloplasty device in the gutter region and the annuloplasty device is secured in place. A second catheter can also be deployed to the gutter to secure the annuloplasty in place while the delivery catheter temporarily holds the annuloplasty device in position. It should be appreciated that the delivery devices and methods for approaching the mitral

valve annulus described above can be used in delivering the annuloplasty device.

In the antegrade approach, the device is introduced through the inferior vena cava IVC or superior vena cava SVC into the right atrium RA, as described above with reference to Figs. 7 and 8. The interatrial septum IAS is then penetrated such as using a catheter 10 having a needle 12, as shown in Figure 7. As shown in Fig. 8, access through the interatrial septum IAS can be maintained by the placement of a guide catheter 14, typically over a guidewire 16. The guide catheter 14 permits introduction to the left atrium LA of a delivery device having the annuloplasty device at a distal end. The delivery device is passed downward through the mitral valve MV such that it approaches the gutter region from below the mitral valve MV. As discussed above, the delivery catheter can be preshaped to facilitate such an approach or it can be equipped with a mechanism that enables the distal region of the delivery catheter to be deflected toward the gutter region.

Alternatively, an annuloplasty ring 520 can be delivered on a balloon catheter 522 as shown in Figs. 79 and 80. The ring 520 can be formed from a deformable material, and the balloon 520 inflated within the valve annulus to expand and deploy the ring, as shown in Fig. 80. The balloon catheter may be placed directly over a guidewire 524, but will more usually be positioned using a combination of a guide catheter and guidewire. Once the ring 520 is deployed, it can be sutured, stapled, glued, or otherwise affixed around the valve annulus.

In an alternative approach that can be used in place of or in combination with deployment of the annuloplasty device, annulus remodeling is accomplished by applying RF energy to the gutter region of the annulus to shrink or otherwise change the annulus shape. A catheter having one or more RF electrodes at a distal tip is inserted through the guide catheter to the gutter region of the annulus. The RF electrodes are energized to deliver energy delivered to the annulus or to the surrounding tissue for remodeling. The catheter can include a suction port

for applying suction to the heart tissue near the annulus to stabilize the device. Again the catheter would be steerable by means of pull wires or the like.

Placement of the annuloplasty device can be combined with any of the other procedures described herein. For example, chordal grasping and/or valve leaflet grasping can be employed in combination with deployment of the annuloplasty device. The annuloplasty device delivery catheter can include grasping arms at a distal end to grasp the valve leaflets during delivery of the annuloplasty device.

Placement of the annuloplasty device can also be combined with temporary or permanent tissue modifications, such as fixation of the valve leaflets or shortening of the chordae, which tissue modifications are described in detail above. With respect to valve leaflet fixation, the delivery catheter that is used to deliver the annuloplasty device can be combined with a suturing tool 200 (shown in Fig. 49) or variations of the suturing tool described herein. The staple applying catheter 300 (shown in Figs. 61a and 61b) can also be used to deliver the annuloplasty device. The stapling mechanism catheter 320 (shown in Fig. 63) can be equipped with a separate lumen for delivery of the annuloplasty device. Pursuant to a method of delivery, one of the catheters described herein is used to apply a clip or staple to the leaflets or to suture the leaflets. Before or after coaptation of the leaflets, the annuloplasty device is deployed in the gutter G of the mitral valve annulus AN. It should be appreciated that any of the delivery or interventional devices described herein can be modified for use with the annuloplasty device.

D. Annuloplasty via the Coronary Sinus

Fig. 94 is a cross-sectional view of the heart showing the mitral valve MV, valve leaflets LF, annulus AN, and coronary sinus CS. The coronary sinus CS is positioned adjacent the mitral valve MV. Because the coronary sinus substantially encircles the mitral valve annulus AN, a re-shaping of the coronary

sinus CS will results in a re-shaping of the annulus AN. A device of predetermined shape can be implanted into the coronary sinus CS and allowed to heal in place so as to form scar tissue adjacent the device. The shape of the device is then subsequently changed to also re-shape the coronary sinus CAS and the adjacent annulus AN in a desired manner. The scar tissue strengthens the tissue to provide a strong attachment to the device and also reduce the risk of injury.

X. DEVICE EMBODIMENTS

The following three device embodiments depict complete device designs utilizing a variety of the specific components described above and/or new component designs to accomplish similar objectives.

A. Atrial Device

Referring to Fig. 83, the atrial device 1000 is comprised of a catheter shaft 1002 having a distal end 1004 and a proximal end 1006. The catheter shaft 1002 is comprised of, among others, a conduit 1008, a coaxial outer sheath 1010, and a central guidewire lumen 1011. Toward the distal end 1004, a pair of stabilizers 1012 having a single-hump shape (previously illustrated in Fig. 31D) are fixedly mounted on the outer sheath 1010 at their proximal end 1014 and fixedly attached or hinged to extenders 1016 at their distal end 1018. The stabilizers 1012 are shown in an outwardly bowed position, however they may be inwardly collapsed by either extending the extenders 1016 or retracting the outer sheath 1010. Bowing may be achieved by the reverse process.

Referring to Fig. 84, the atrial device 1000 may be used with a typical antegrade approach to the mitral valve MV. As previously described and depicted in Figs. 7 and 8, such an antegrade approach may involve penetrating the interatrial septum IAS and maintaining such access with a guide catheter 14. The guide catheter 14 permits introduction of the atrial device 1000 to the left

atrium LA and mitral valve MV. To allow passage of the device 1000 through the guide catheter 14, the stabilizers 1012 must be in a collapsed position as shown. In addition, graspers, described below, may be fully retracted to avoid damage to cardiac structures. Thus, they are not visible in Fig. 84.

Referring to Fig. 85, the atrial device 1000 may be stabilized against the mitral valve MV. The stabilizers 1012 may be inserted through the mitral valve MV and may be aligned with the line of coaptation C between the valve leaflets LF1, LF2. To minimize mitral valve regurgitation (MVR) due to insertion of the device 1000, the stabilizers 1012 may be located approximately 120 degrees apart. This angle may be fixed or adjustably variable. The single-humped shape of the stabilizers 1012 may allow the inferior portion 1030 to pass within the valve and apply radial pressure to the commissures CM and the superior portion 1032 (or hump) to rest upon and apply axial pressure to the commissures CM.

Referring again to Fig. 83, a pair of graspers, comprised of grasping sheaths 1020 and three opposing prongs 1021 configured to partially or fully penetrate or pierce, are shown extended from the conduit 1008 in the plane bisecting the angle of the stabilizers 1012 (i.e. approaches the middle of the leaflets). This angle may be fixed or variable. When not in use, however, the graspers may be fully retracted within the conduit 1008. Tension from lateral steering wires 1022 cause the graspers to deflect away from each other and approximate the most desirable angle for grasping. Amount of deflection may be controlled from the proximal end of the device by the steering wires 1022. When the graspers are positioned in a desired location as shown in Fig. 85, the prongs 1021 may be deployed and opened by either retraction of the grasping sheath 1020 or advancement of the prongs 1021 beyond the grasping sheath 1020. Retraction of the sheath 1020 does not significantly affect the position of the graspers, thus enabling the user to contact the valve leaflets LF1, LF2 with the prongs 1021 housed within the sheath 1020 and then to initiate grasping the leaflets at the contacted location by retracting the grasping sheaths 1020. The

opposing prongs 1021 may be closed to grasp (pinch, partially penetrate or pierce) the leaflet tissue by advancing the grasping sheaths 1020 or retracting the prongs 1021 within the sheaths 1020.

After both leaflets have been grasped, tension in the steering wires 1022 is released and the conduit 1008 is advanced over the grasping sheaths 1020. Such advancement draws the sheaths 1020, and grasped leaflets, together for coaptation. After coaptation, the mitral valve regurgitation is evaluated to determine if the locations which are grasped are appropriate for fixation. If the grasping points are not appropriate, the leaflets may be released and regrasped individually or simultaneously by the above described methods. If the grasping points are appropriate, the preferred embodiment allows for exchange of the guidewire, located in the guidewire lumen 1011, for a fixation device. The fixation device may use, for example, staples, sutures, clips, rivets, coils, fusing devices, zippers, snares, clamps, hooks, chordal fixation or shortening devices to repair the mitral valve regurgitation. Specifically, the fixation device may be the hollow suturing coil 1300 shown previously in Figs. 49A-C. As shown in Fig. 84A, the hollow suturing coil 1300 containing suture 1302 (not shown) may be deployed through the guidewire lumen 1011 in a coiled configuration. The coil 1300 may expand or change shape once it is deployed from the lumen 1011, providing the coil 1300 is comprised of a suitable shape memory or superelastic material. Similarly, as shown in Fig. 84B, the suturing coil 1300 may be deployed through the guidewire lumen 1011 in a straightened configuration such that it coils and/or expands or changes shape once it is deployed from the lumen 1011.

The above described components may be manipulated and controlled by a handle 1026 connected to the proximal end 1006 of the catheter shaft 1002, as shown in Fig. 83. The handle 1026 permits independent control of the components, including but not limited to retraction and extension of extenders 1016, deployment of stabilizers 1012, adjustment and locking of outer sheath 1010, translation and deflection of grasping sheaths 1020, stopping and locking

of grasping sheaths 1020 and axial sliding of the conduit 1008. In addition, the device may be readily adapted to approach the mitral valve trans-atrially for a minimally invasive surgical (MIS) procedure, with either beating or stopped heart.

B. Atrial-Ventricular Device

Referring to Fig. 86, the atrial-ventricular device 1100 is comprised of a catheter shaft 1102 having a distal end 1104 and a proximal end 1106. The catheter shaft 1102 is comprised of, among others, a conduit 1108, a coaxial outer sheath 1110, a central lumen 1111 through which a double-jaw grasper 1113 may be inserted, and a central guidewire lumen 1105. Toward the distal end 1104, a pair of stabilizers 1112 having a triangular shape (previously illustrated in Fig. 31A) are fixedly mounted on the outer sheath 1110 at their proximal end 1114 and fixedly attached to extenders 1116 at their distal end 1118. The stabilizers 1112 are shown in an outwardly bowed position, however they may be inwardly collapsed by either extending the extenders 1116 or retracting the outer sheath 1110. Bowing may be achieved by the reverse process. The double-jaw grasper 1113 is comprised of two articulating jaw arms 1120 which may be opened and closed against the central shaft 1122 (movement depicted by arrows) either independently or in tandem. The grasper 1113 is shown in the open position in Fig. 86. The surfaces of the jaw arms 1120 and central shaft 1122 may be toothed, as shown, or may have differing surface textures for varying degrees of friction.

Referring to Figs. 87A-C, the atrial-ventricular device 1100 may be used with a typical antegrade approach to the mitral valve MV, as previously described and depicted in Figs. 7 and 8. However, the double-jaw grasper 1113 extends through the valve such that the leaflets L1, L2 are grasped from below. Thus, the device 1100 is termed "atrial-ventricular."

Referring to Fig. 87A, the atrial device 1100 may be stabilized against the mitral valve MV. The stabilizers 1112 may be positioned on the superior surface

of the valve leaflets LF1, LF2 at a 90 degree angle to the line of coaptation. The grasper 1113 may be advanced in its closed position from the conduit 1108 between the leaflets LF1, LF2 until the jaw arms 1120 are fully below the leaflets in the ventricle. At this point, the grasper 1113 may be opened and retracted so that the jaw arms 1120 engage the inferior surface of the leaflets LF1, LF2. In this manner, the leaflets are secured between the stabilizers 1112 and the jaw arms 1120. This action allows for leaflets of many different shapes and orientations to be secured. Cardiomyopathic valves are often enlarged and distorted so that they coapt irregularly. Such irregularity creates difficulty in mechanically coapting such valves for tissue modification. The action of the grasper 1113 overcomes much of these difficulties.

Referring to Fig. 87B, the grasper 1113 will gradually close, drawing the leaflets LF1, LF2 together while maintaining a secure hold on the leaflets between the jaw arms 1120 and the stabilizers 1112. This may be accomplished by number of methods. For example, the stabilizers 1112 may be gradually collapsed by either extending the extenders 1116 or retracting the outer sheath 1110. As the stabilizers 1112 collapse, the jaw arms 1120 may collapse due to spring loading to gradually close the grasper 1113. Alternatively, the jaw arms 1120 may be actuated to close against the central shaft 1122 applying force to the stabilizers 1112 causing them to collapse. In either case, such action allows the stabilizers 1112 to simultaneously vertically retract and withdraw from the leaflets as the leaflets are clamped between the jaw arms 1120 and the central shaft 1122. In this manner, the leaflets are effectively "transferred" to the grasper 1113. Referring to Fig. 87C, once the collapsed stabilizers 1112 are completely withdrawn, the leaflets LF1, LF2 are held in vertical opposition by the grasper 1113 in a more natural coaptation geometry. At this point the leaflets may be adjusted and fixated. Fixation may be achieved with an external element or the grasper 1113 may be left in place as a fixation device.

The above described components may be manipulated and controlled by a handle 1126 connected to the proximal end 1106 of the catheter shaft 1102, as shown in Fig. 86. The handle 1026 permits independent control of the components described above.

C. Ventricular Device

Referring to Fig. 88, the ventricular device 1200 is comprised of a catheter shaft 1202 having a distal end 1204 and a proximal end 1206. The distal end 1204 is comprised of a joining coil 1208, an upper jaw 1210, a lower jaw 1212, an actuator 1214 and a central lumen 1216 through which a guidewire 1218 or other wires may be inserted. The upper jaw 1210 may open and close (depicted by arrows) against the lower jaw 1212 by action of the actuator 1214. The upper jaw 1210 is shown in the open position. These components may be manipulated and controlled by a handle 1226 connected to the proximal end 1206 of the catheter shaft 1202 as shown.

Referring to Figs. 89, the ventricular device 1200 may be used with a typical retrograde approach to the mitral valve MV, as previously described and depicted in Fig. 9. Here the mitral valve MV may be accessed by an approach from the aortic arch AA across the aortic valve AV, and into the left ventricle LV below the mitral valve MV. Such access may be maintained with a guide catheter 40 through which the ventricular device 1200 may be introduced. The ventricular device 1200 may be inserted through the guide catheter 40 with the upper jaw 1210 in the closed position. After it exits the guide catheter 40 just below the aortic valve AV, the device 1200 may be advanced toward the mitral valve MV. The catheter shaft 1202 may be pre-shaped to provide favorable curvature in positioning the distal end 1204 beneath the valve leaflets ALF, PLF. Additionally, two mandrels with favorable shapes may be advanced into a lumen in the catheter shaft 1202. By changing the location of the mandrels with respect

to each other and to the catheter shaft 1202, the general curvature of the shaft 1202 may be altered in-situ.

It is desired to position the distal end 1204 of the device 1200 beneath the mitral valve leaflets ALF, PLF with the upper jaw 1210 in the open configuration. The lower jaw 1212 is to be proximal to the anterior leaflet ALF and the upper jaw 1210 is to be distal of the posterior leaflet PLF, as shown in Fig. 89, such that the leaflets may be secured between the jaws 1210, 1212. To achieve such positioning, the device 1200 may be required to flex at an extreme angle in the region of the joining coil 1208. Therefore, the joining coil 1208 is designed to provide such flexibility.

To aid in positioning the device 1200, a balloon wire 1250 may be used. The balloon wire 1250 may first be inserted through the aortic valve AV, advanced down to the apex of the ventricle and then back upwards towards the mitral valve MV behind the posterior leaflet PLF. Once positioned, the balloon 1252 may be inflated to assist in holding the position stationary. A cuff wire 1260 may then be inserted through the aortic valve AV. The cuff wire 1260 may track along the balloon wire 1250 by means of a locking ring 1262. The cuff wire 1260 may track down to the apex of the ventricle and then back upwards toward the mitral valve MV. Once the cuff wire 1260 is advanced to a desirable position, the locking ring 1262 may be actuated to lock the cuff wire 1260 to the balloon wire 1250. A typical means of actuation is by inflation of the locking ring. 1262. The ventricular device 1200 may then be tracked over the cuff wire 1260 to the desired position, as shown in Fig. 89. The balloon, or balloon wire 1250, may also be used to walk or urge the posterior leaflet towards the center of the valve to facilitate grasping.

Once positioned, the upper jaw 1210 may be closed against the lower jaw 1212 such that the leaflets are grasped between them. It is often desirable to adjust or manipulate the leaflets once they are grasped. Manipulation should occur only in a superior/inferior (up/down) motion in order to bring the leaflets to

a final position where regurgitation is minimized. The lower jaw 1212 may be fitted with a travel mechanism for extending or retracting the jaw 1212. This would move one leaflet up or down with respect to the other leaflet. Once the leaflets are sufficiently adjusted, fixation may occur in any manner previously described. In a preferred embodiment, fixation may achieved through the lower jaw 1212, as depicted in Figs. 90A and 90B. As shown in Fig. 90A, a cutout 1270 may be present in the lower jaw 1212 accessing a lumen 1272 which extends through the catheter shaft 1202 and lower jaw 1212; such a lumen may also serve as the guidewire lumen 1216. When the upper jaw 1210 is closed against the lower jaw 1212, the valve leaflets LF may be captured between the jaws. As shown a side-view, Fig. 90B, the captured leaflets LF may protrude into through the cutout 1270 into the lumen 1272. A fixation device 1274 may then be inserted through the lumen 1272 (in the direction of the arrow) and may affix the leaflets LF together. It may be appreciated that such a method of fixation may be used in a number of devices involving jaw-type graspers, such as the atrial ventricular device 1100 depicted in Fig. 86.

Although the forgoing devices and methods have been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that various alternatives, modifications and equivalents may be used and the above description should not be taken as limiting in scope.

CLAIMS

1. A method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having at least one structure releasably coupled thereto;

deploying the structure from the catheter into a gutter on a ventricular side of annulus of the heart valve, the structure adapted to modify the annulus so as to reduce regurgitation in the heart valve; and

in combination with deploying the structure, holding leaflets of the heart valve together so as to reduce regurgitation in the heart valve.

2. A method as in claim 1, wherein advancing the catheter comprises

advancing the catheter into the right atrium;

penetrating the interatrial septum to form an opening in the interatrial septum;

advancing the catheter through the opening in the interatrial septum into the left atrium ;

advancing catheter downward through the mitral valve.

3. A method as in claim 2, further comprising deflecting a distal region of the catheter upwardly toward the gutter such that the structure approaches the gutter from below the mitral valve.

4. A method as defined in claim 1, wherein holding the leaflets of the valve together comprises permanently attaching opposed points on or along the valve leaflets together.

5. A method as defined in claim 1, wherein holding the leaflets of the valve together comprises suturing, clipping, stapling, riveting, gluing, or fusing opposed points on or along the valve leaflets together.

6. A method as defined in claim 1, wherein holding the leaflets of the valve together is accomplished by linking opposed chordae of the valve leaflets together.

7. A method as defined in claim 8, wherein linking comprises suturing, capturing, fusing, clipping, or gluing the opposed chordae.

8. A method as in claim 1, wherein modifying the annulus comprises circumferentially shortening the annulus.

9. A method as in claim 1, wherein the structure comprises a ring that at least partially surround the annulus within the gutter.

10. A method as in claim 1, wherein the structure comprises a plurality of staples positioned in an annular formation in the gutter about the annulus.

11. A method as in claim 1, wherein the structure includes at least one securing member that secures the structure in the gutter.

12. A method as in claim 1, wherein the heart valve comprises the mitral valve.

13. A method as in claim 1, further comprising:

permitting scar tissue to grow around the structure within the gutter;

re-shaping the structure in order to modify the shape of the annulus, wherein the scar tissue provides a strengthened attachment between the structure and the gutter.

14. A method as in claim 13, wherein the structure is re-shaped after passage of a period of time comprising four to twenty four weeks.

15. A method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having an annuloplasty device releasably coupled thereto;

performing an intervention on a gutter on a ventricular side of the heart valve to modify an annulus of the heart valve and reduce regurgitation in the heart valve;

in combination with performing an intervention, modifying a spatial relationship between a first valve leaflet and a second valve leaflet of the heart valve so as to reduce regurgitation in the heart valve.

16. A method as in claim 15, wherein performing an intervention comprises applying RF energy to the gutter in order to change the shape of the annulus.

17. A method as in claim 15, wherein performing an intervention comprises deploying a structure from the catheter into the gutter.

18. A method as in claim 15, further comprising:

permitting scar tissue to grow around the structure within the gutter;

re-shaping the structure in order to modify the shape of the annulus, wherein the scar tissue provides a strengthened attachment between the structure and the gutter.

19. A method as in claim 18, wherein the structure is re-shaped after passage of a period of time comprising four to twenty four weeks.

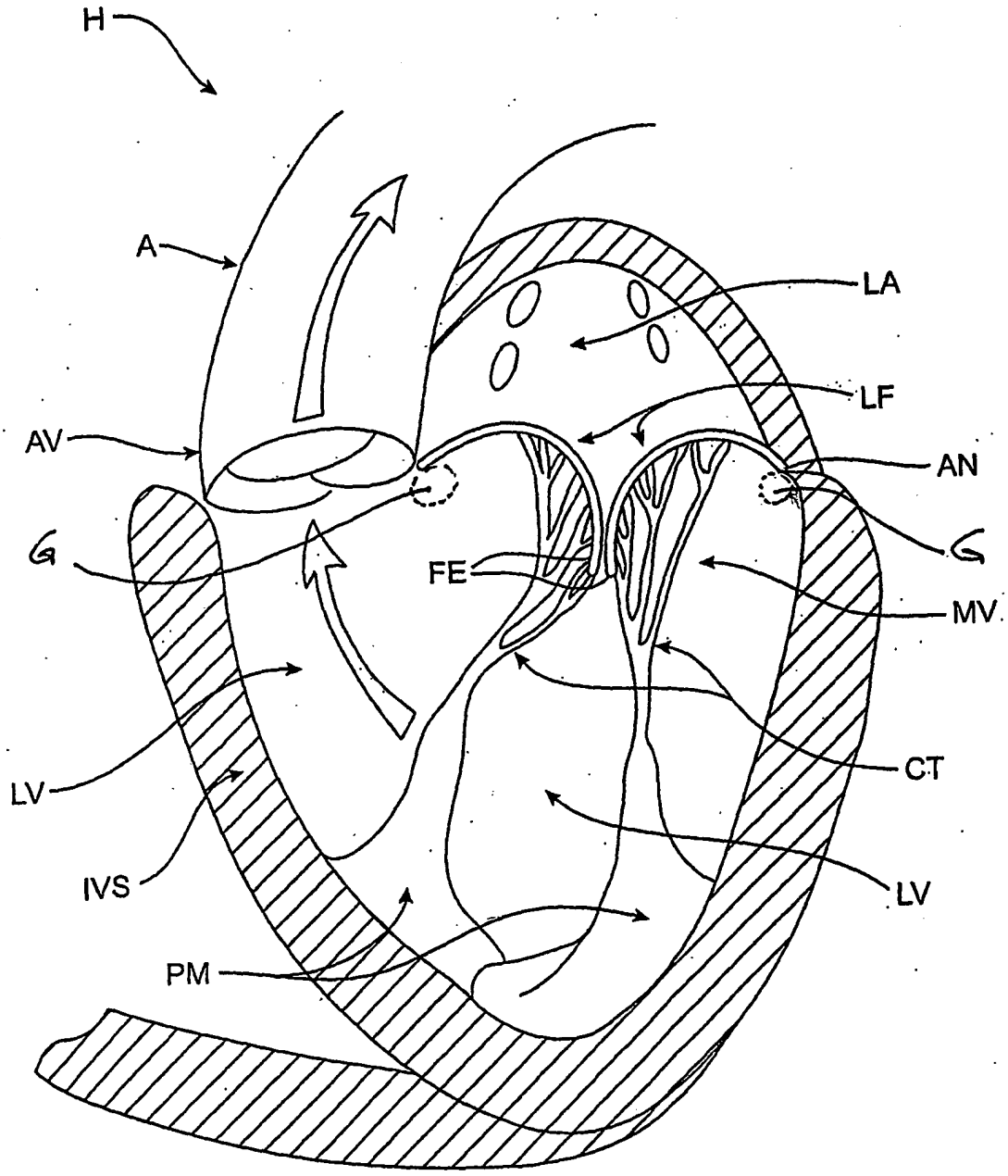


FIG. 1

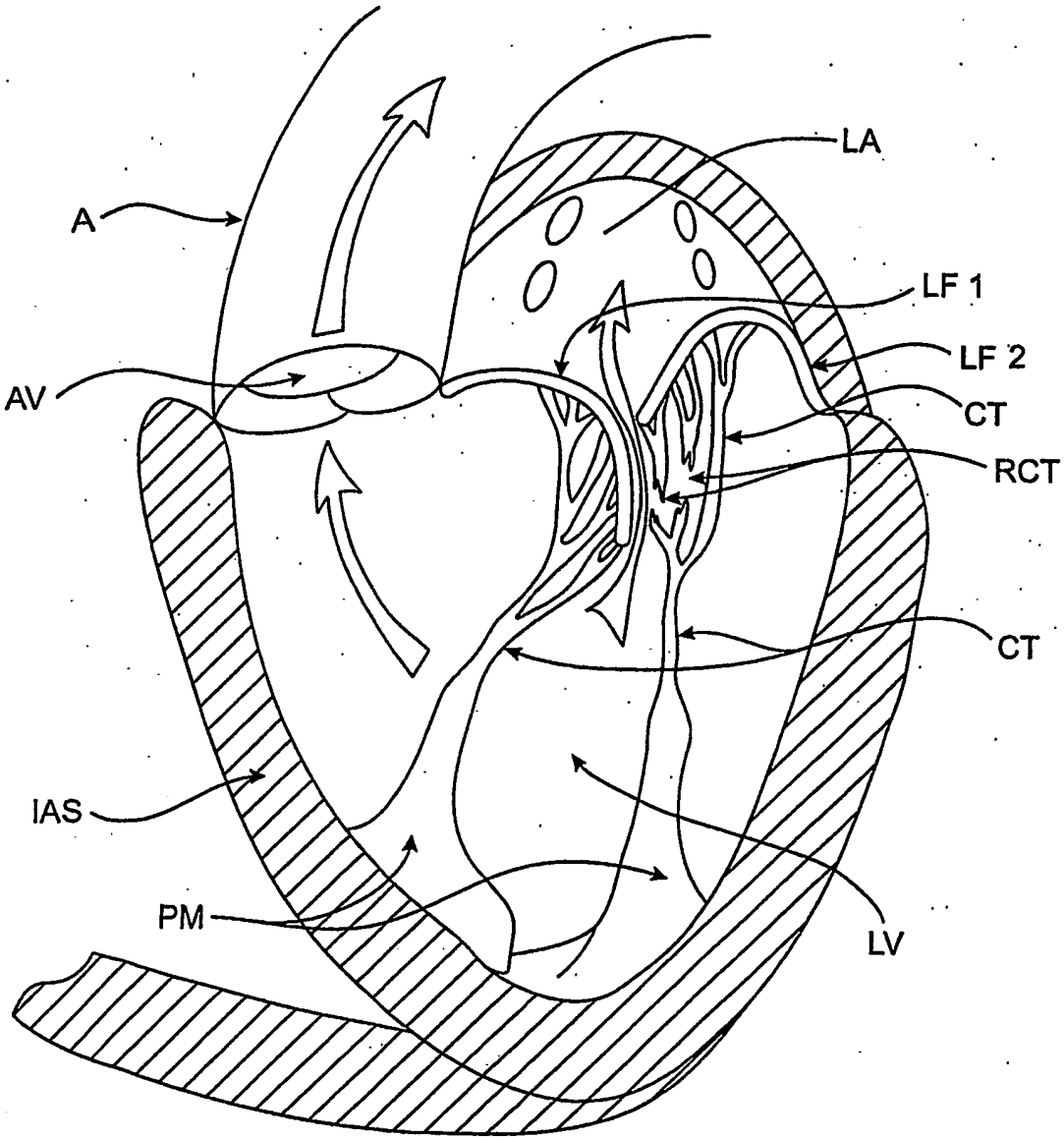


FIG. 2

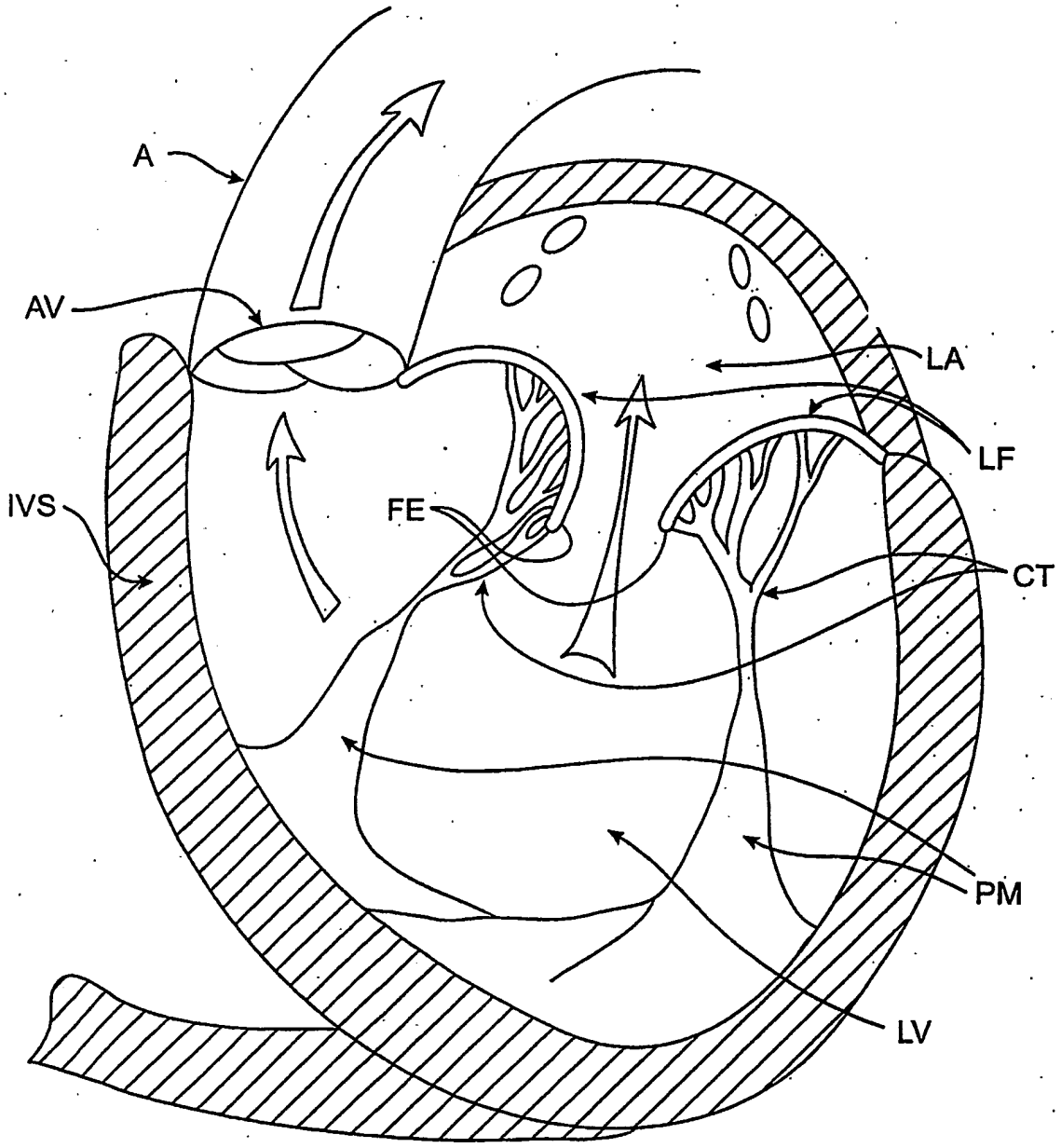


FIG. 3

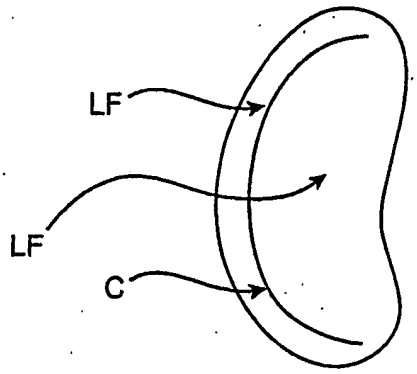


FIG. 3A

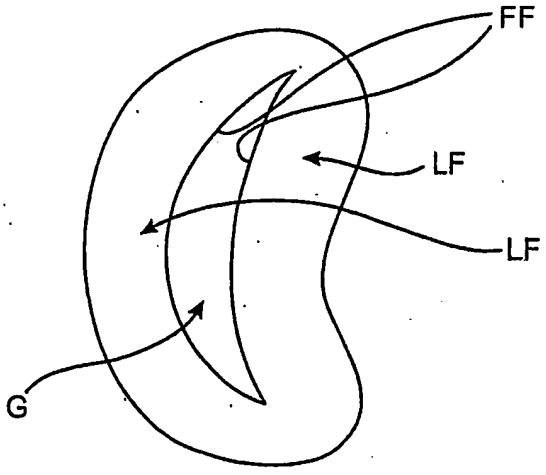


FIG. 3B

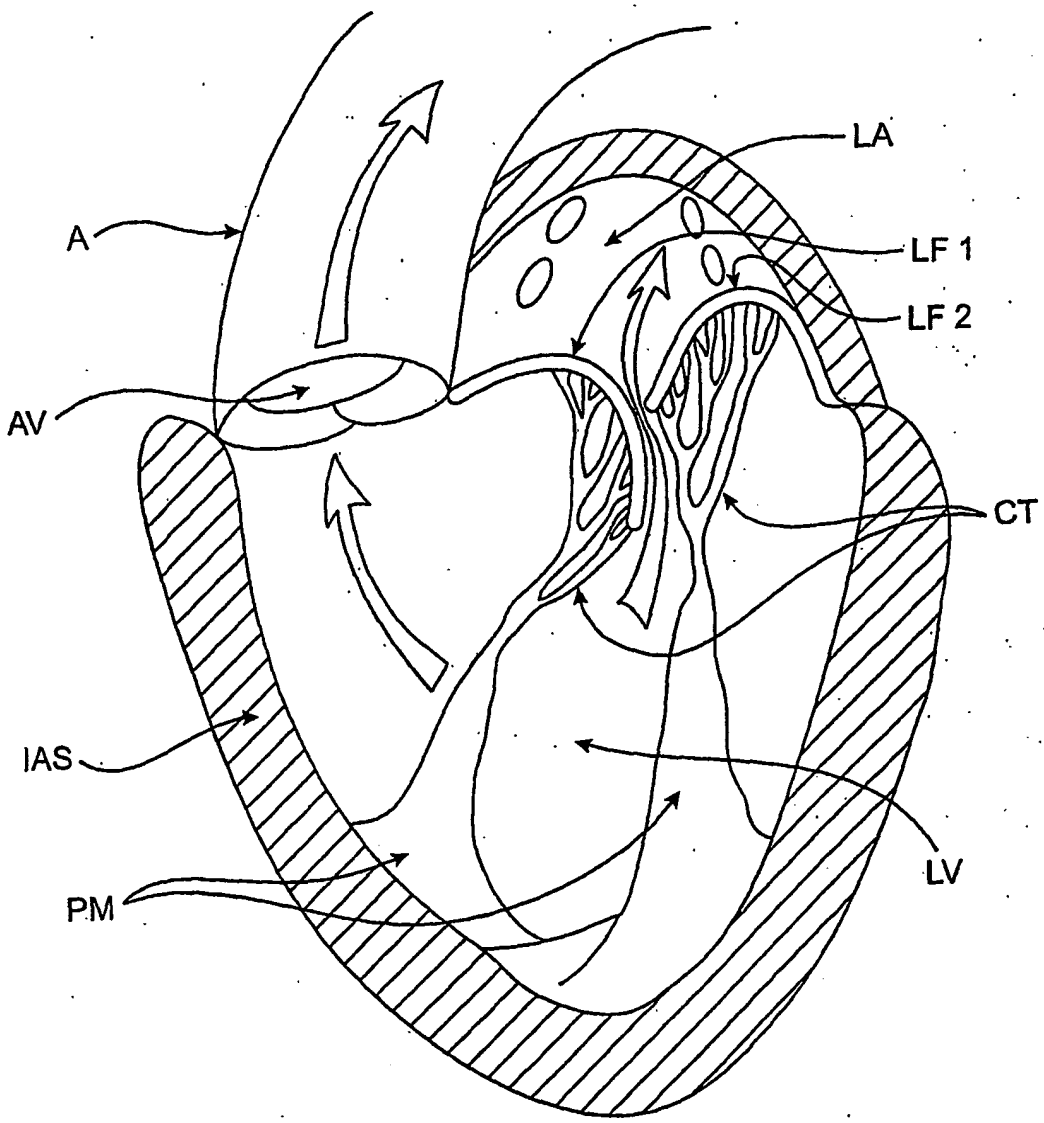


FIG. 4

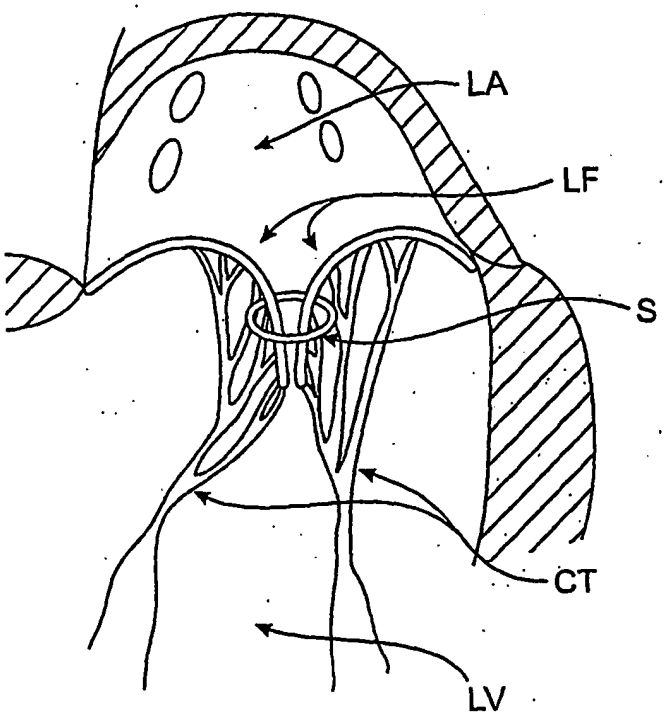


FIG. 5

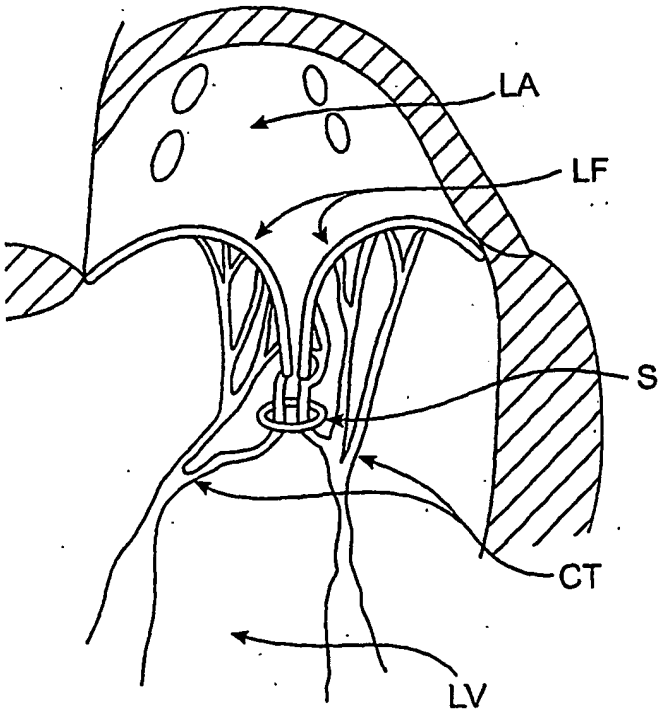


FIG. 6

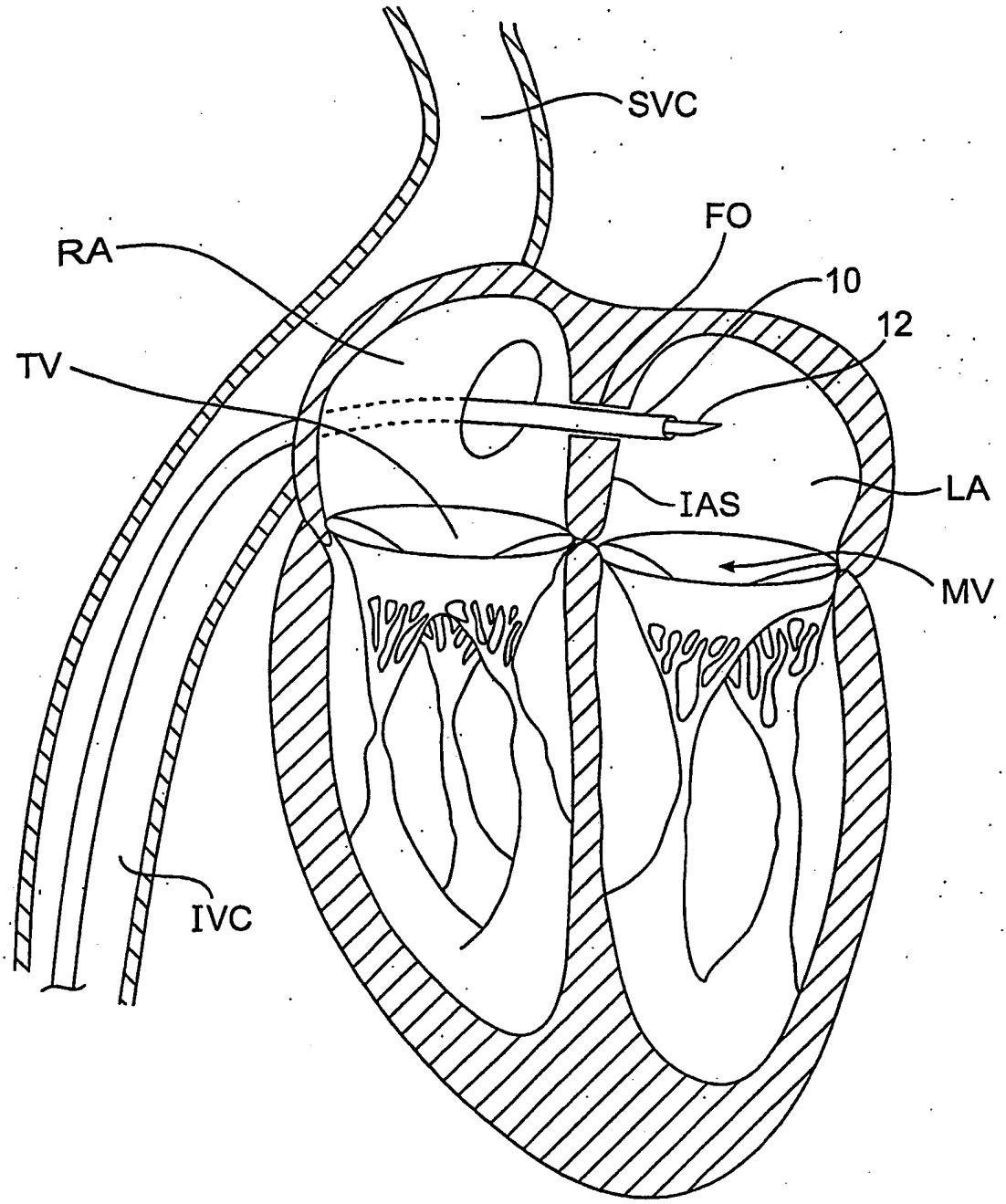


FIG. 7

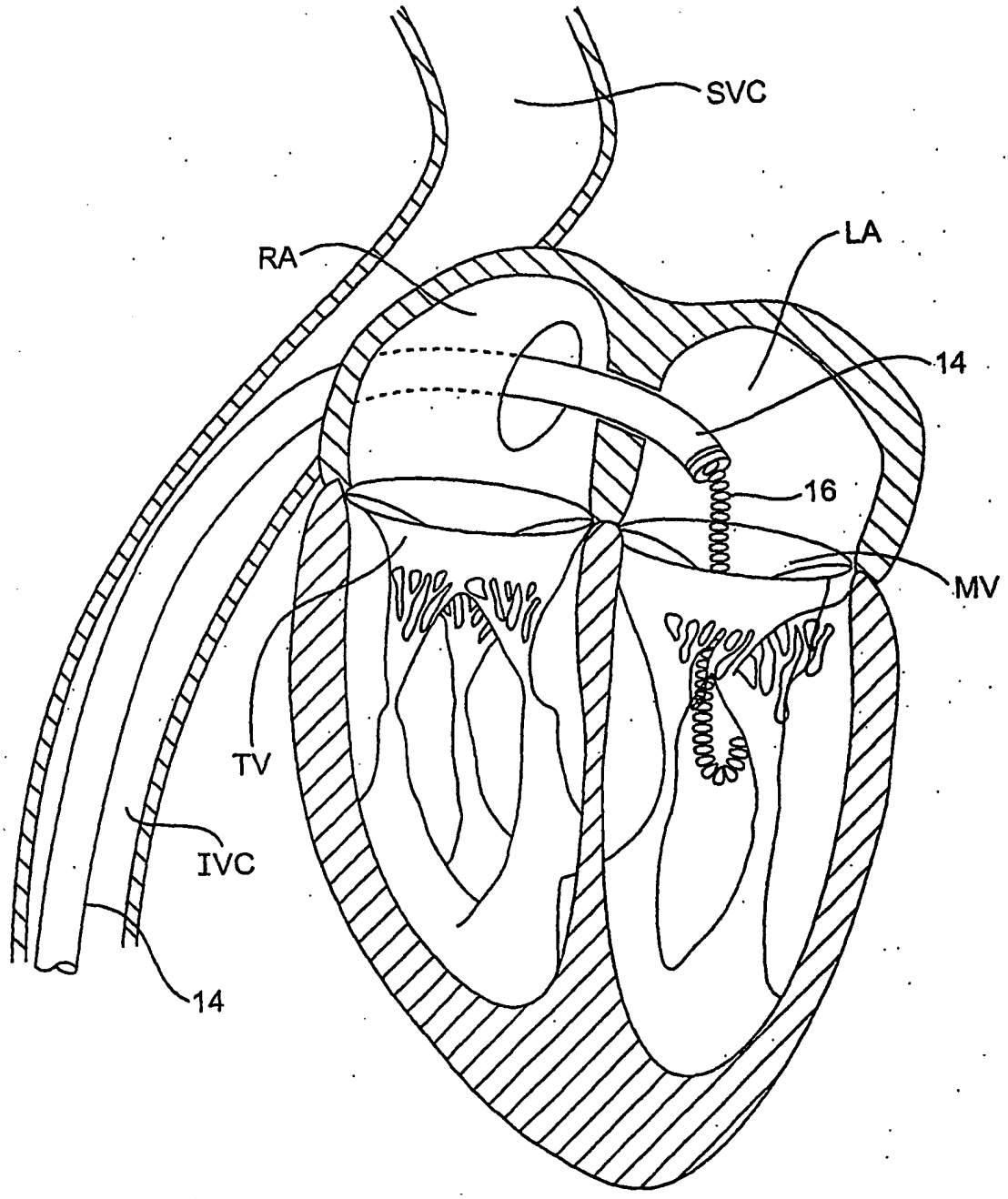


FIG. 8

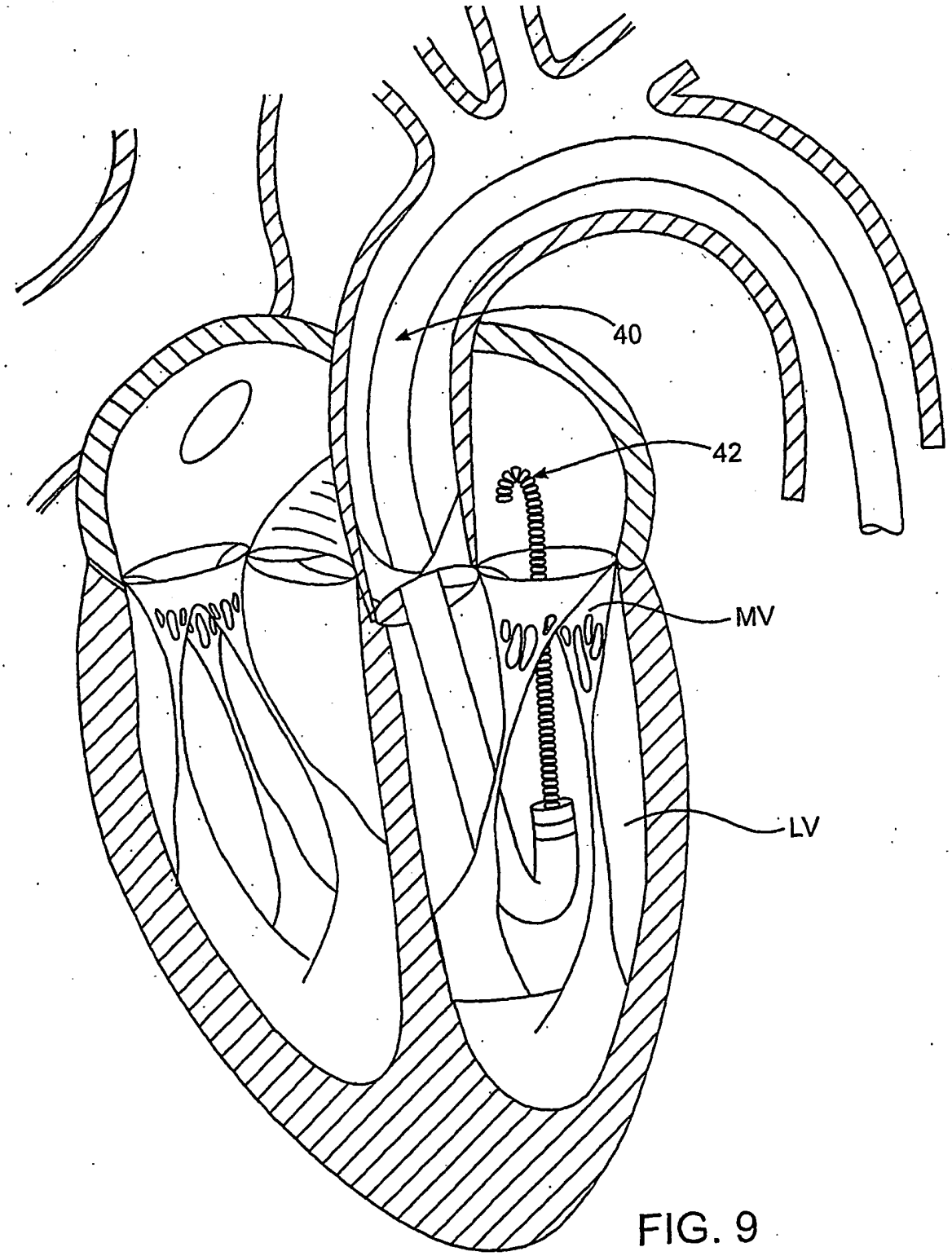


FIG. 9

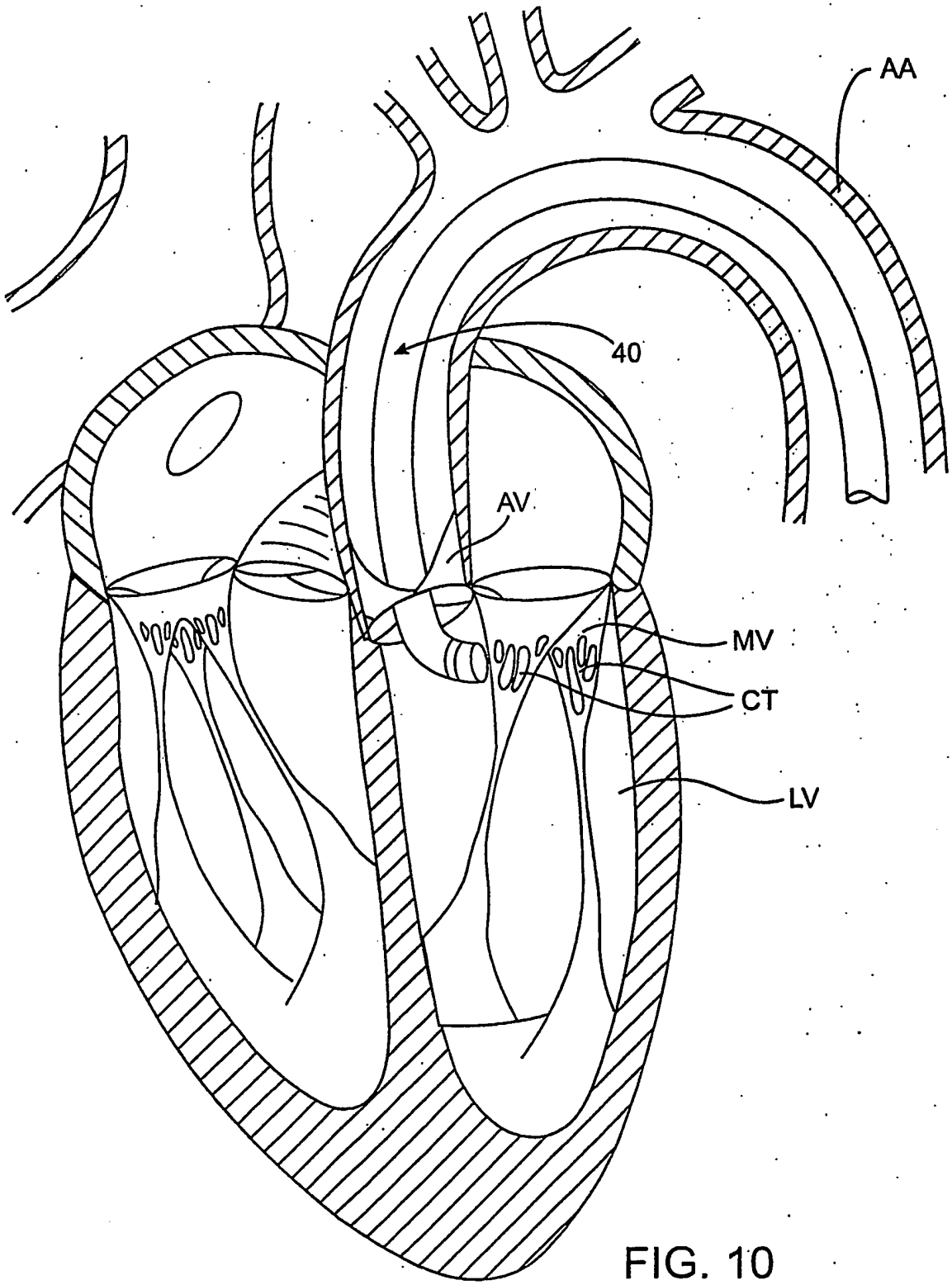


FIG. 10

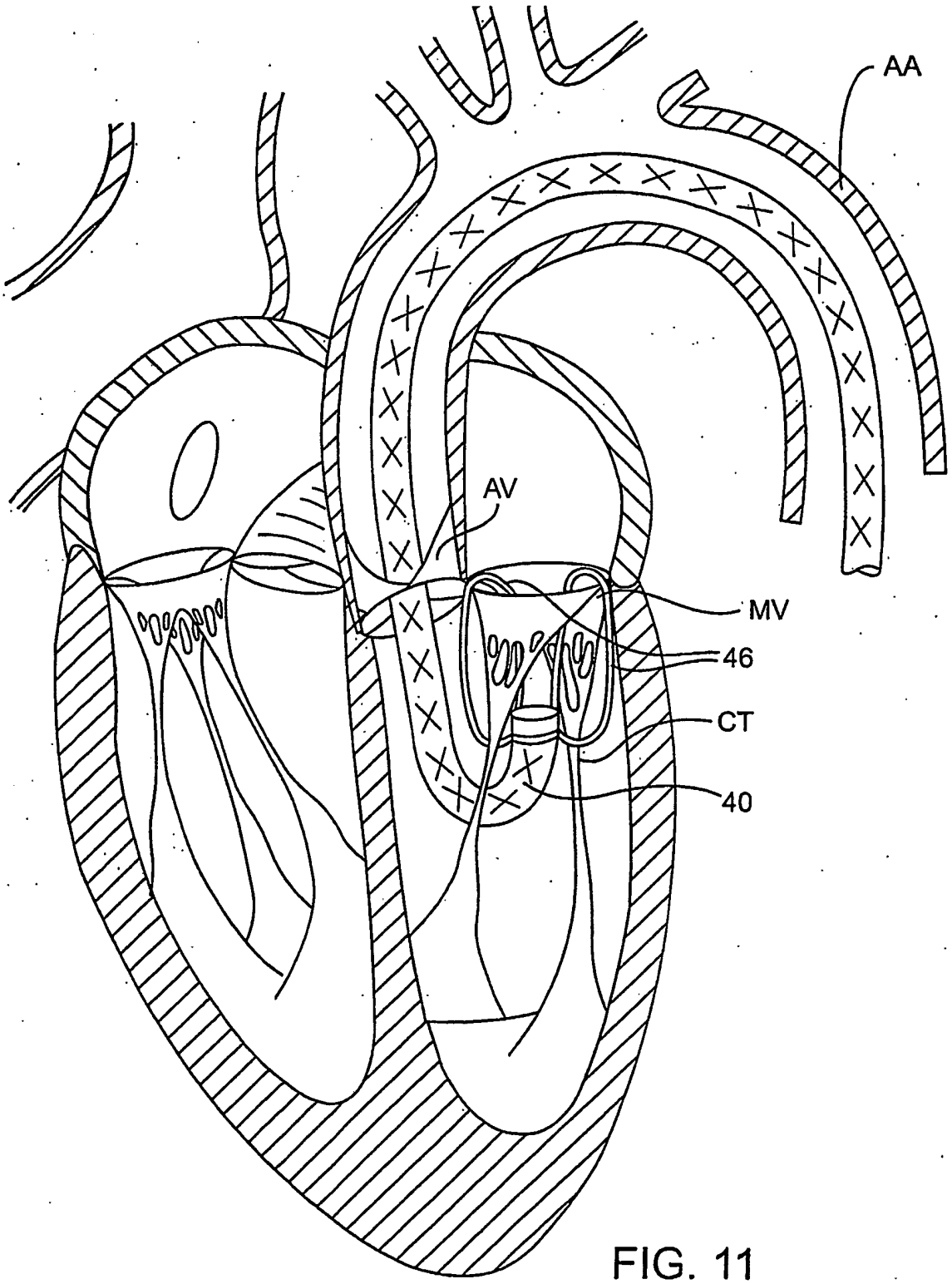


FIG. 11

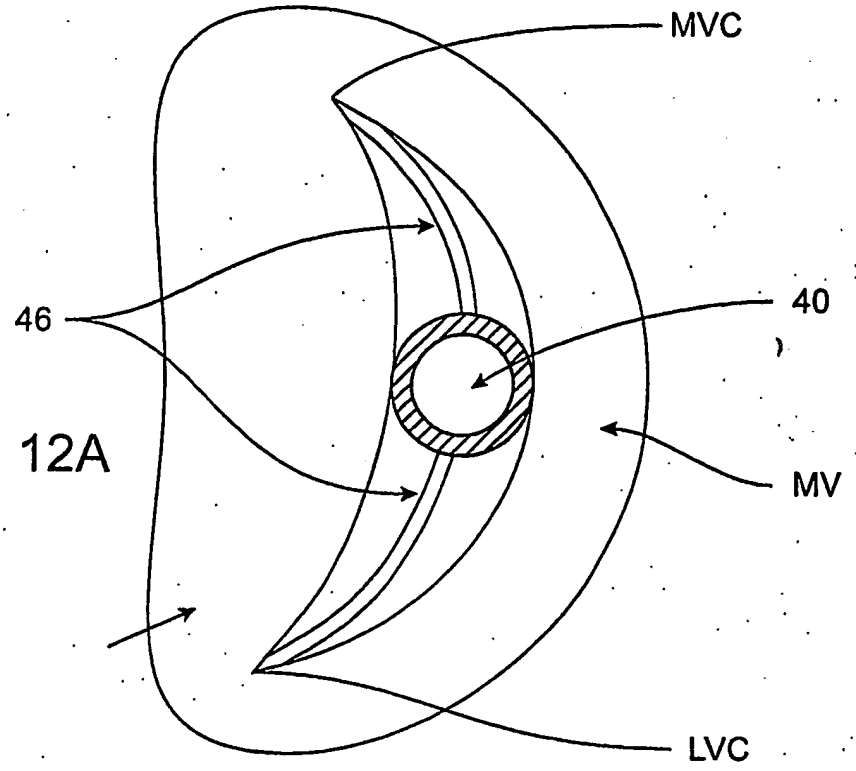


FIG. 12A

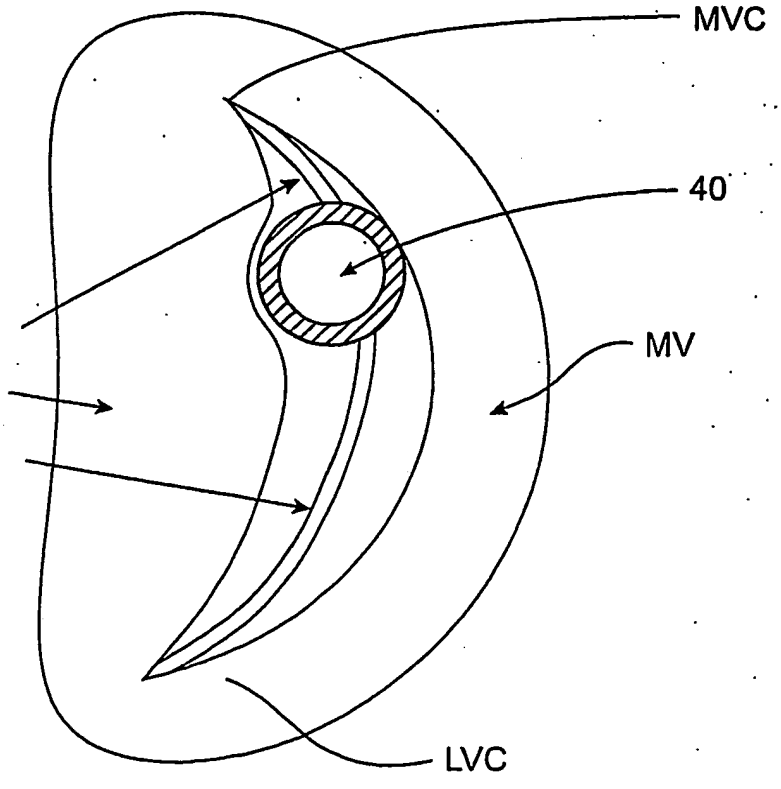


FIG. 12B

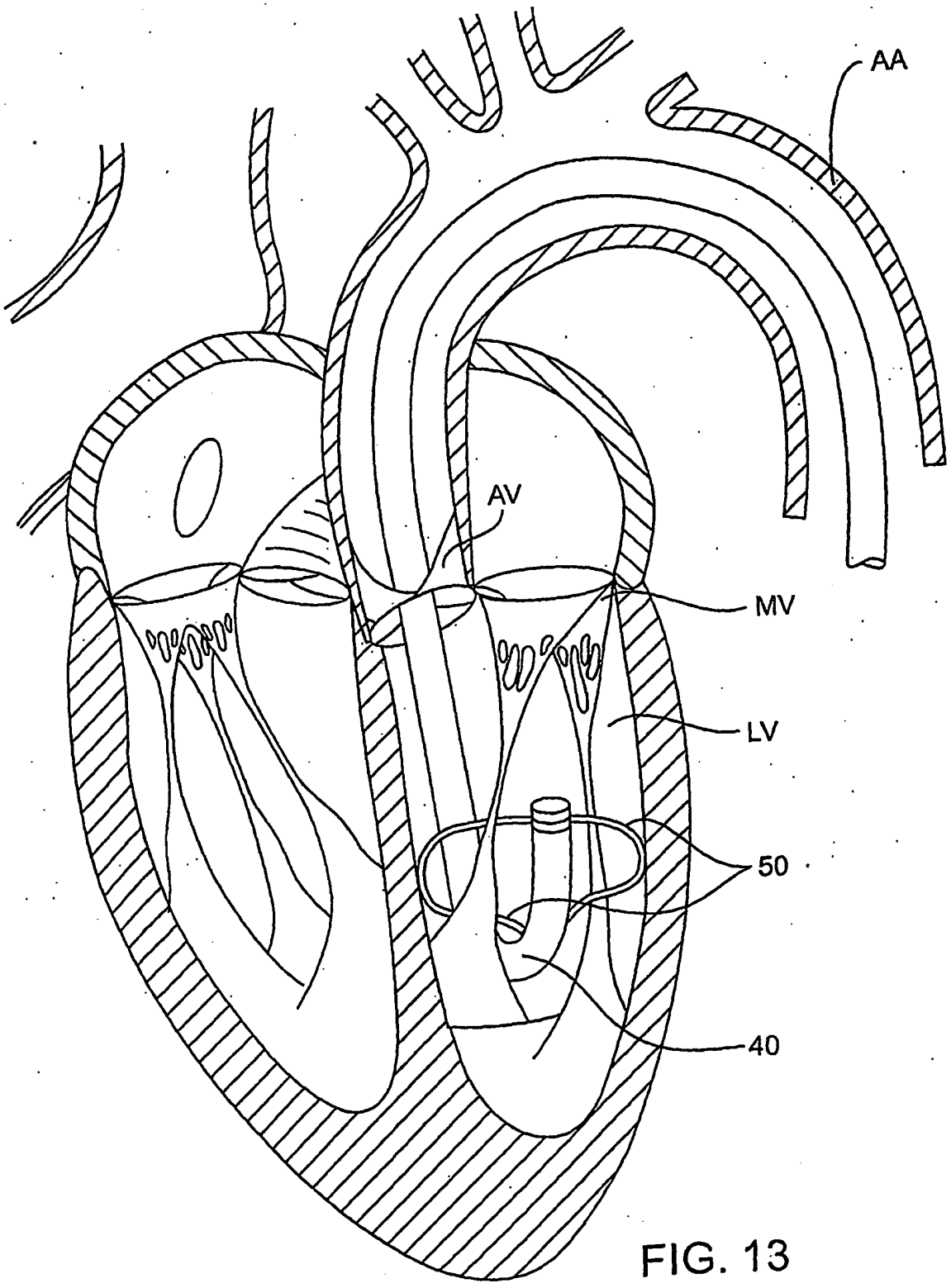


FIG. 13

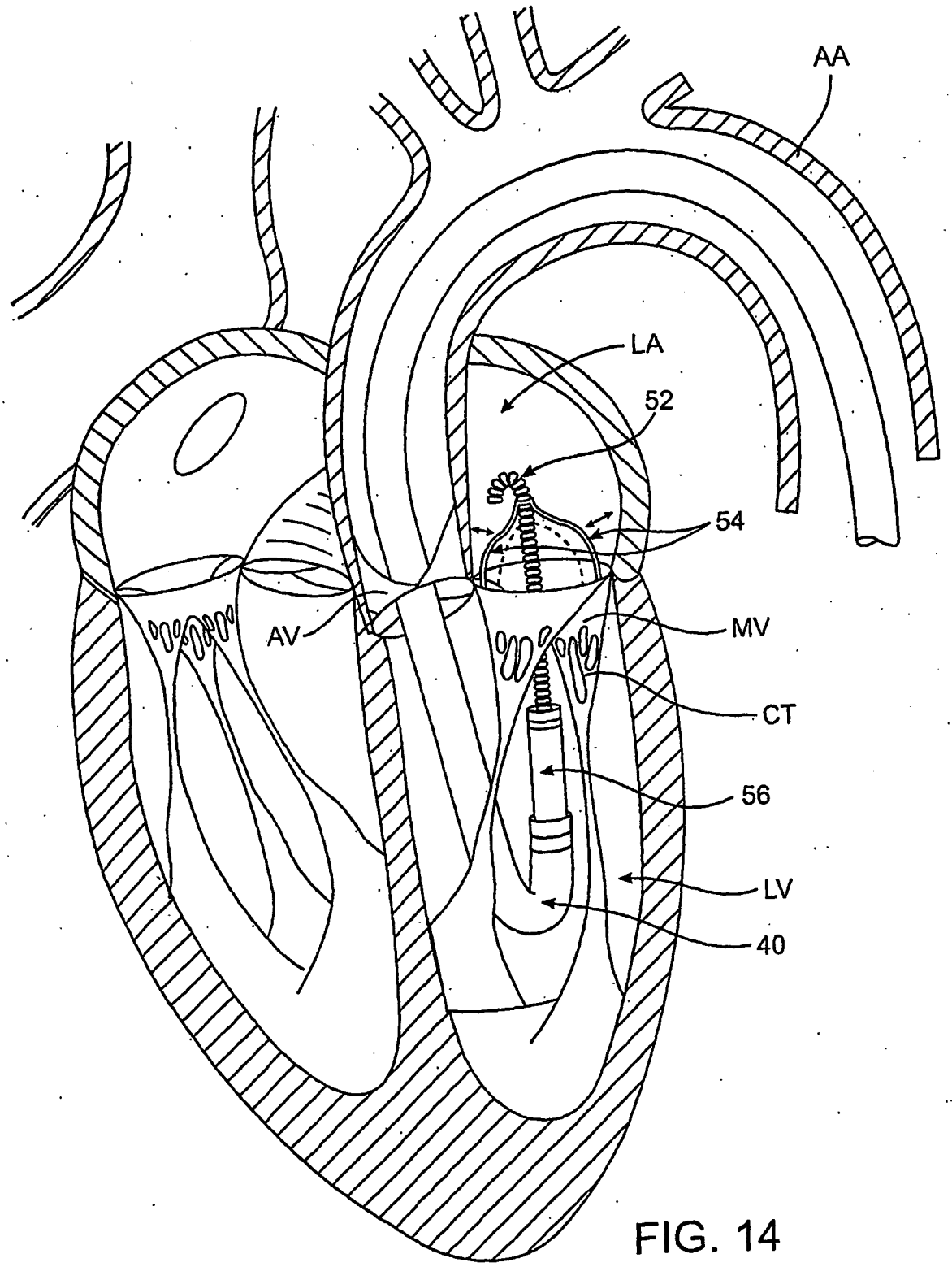


FIG. 14

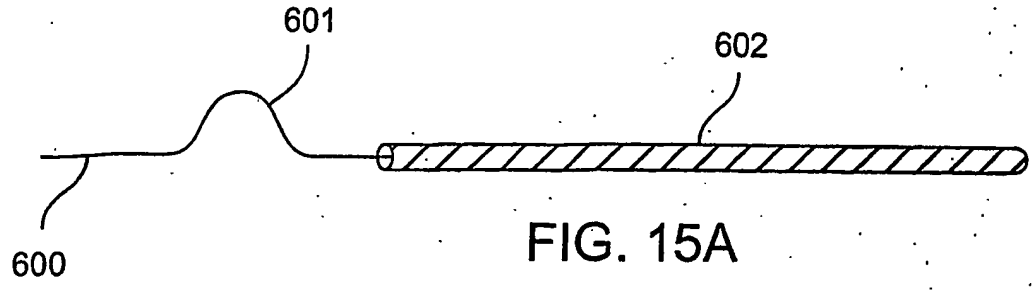


FIG. 15A

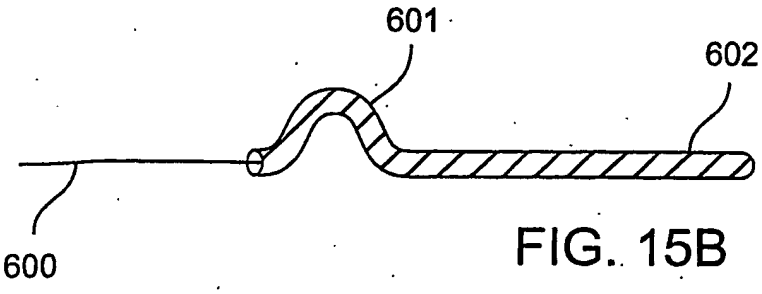


FIG. 15B

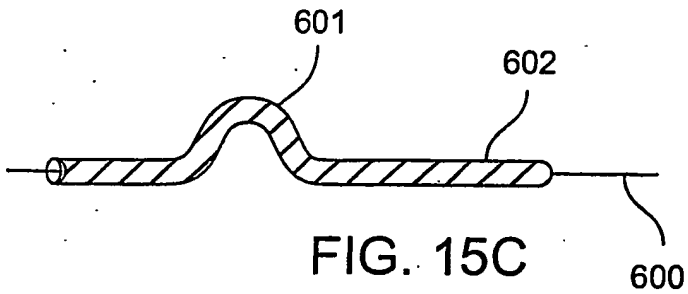


FIG. 15C

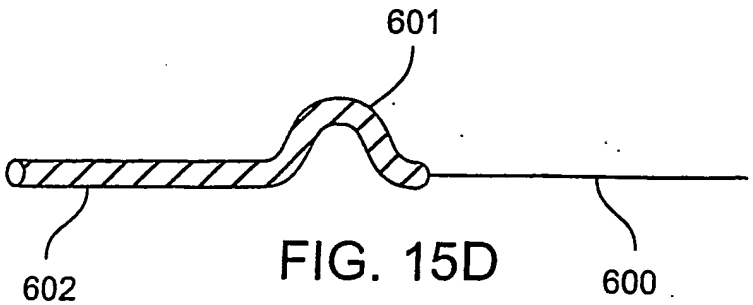


FIG. 15D

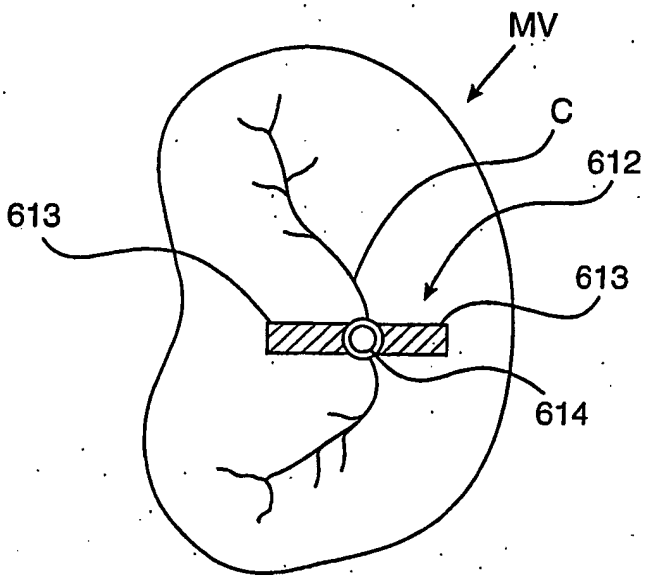


FIG. 16

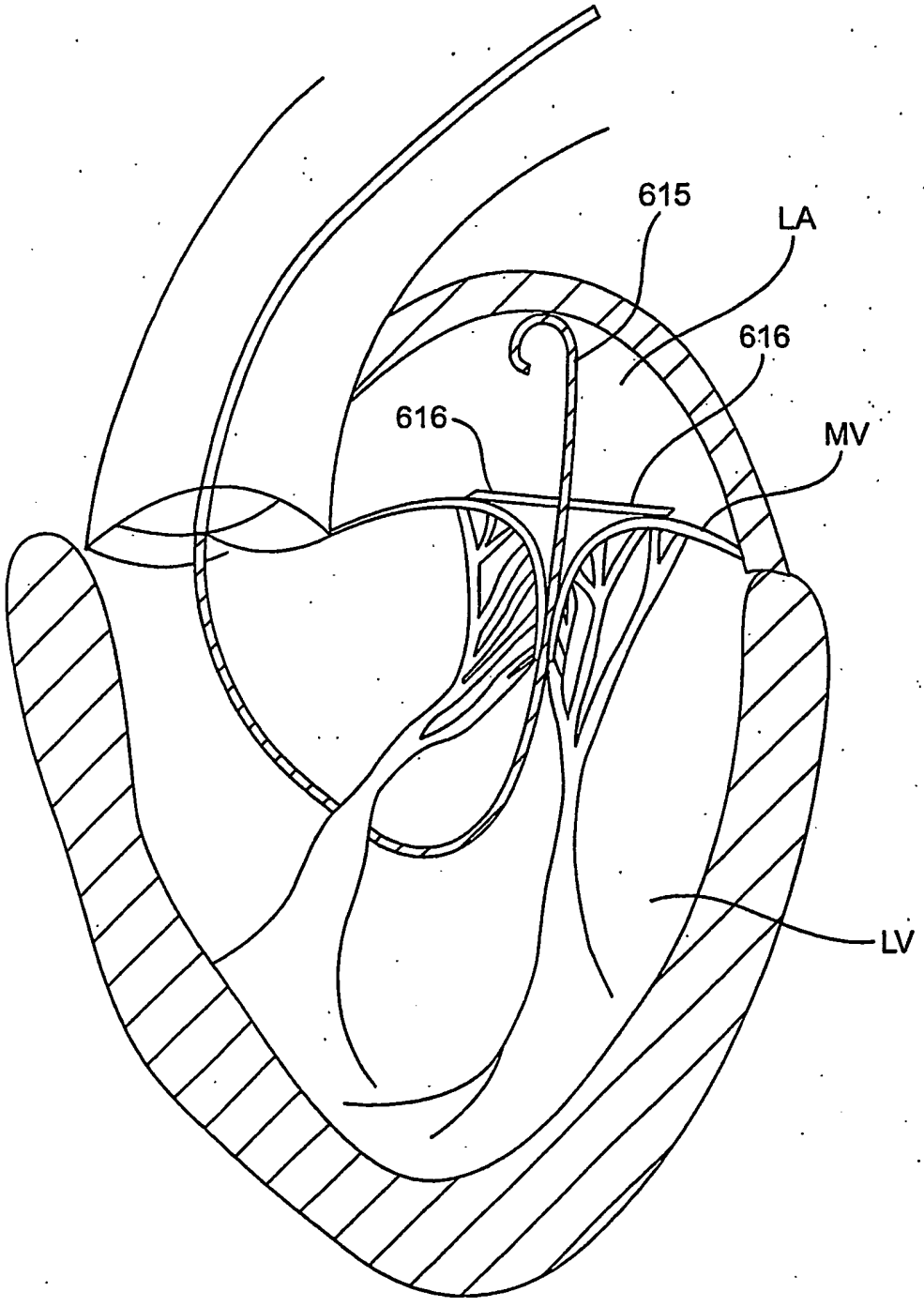


FIG. 17

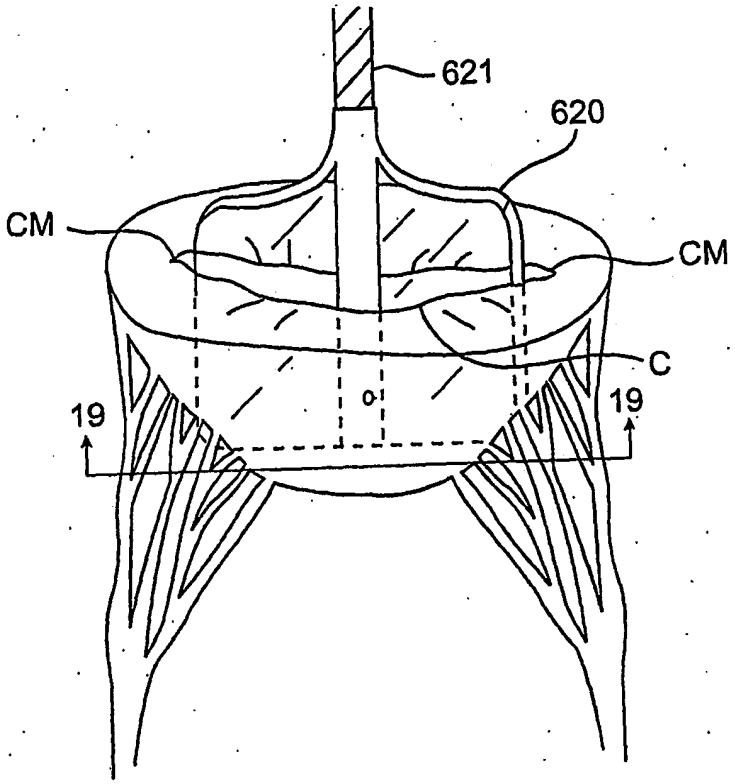


FIG. 18

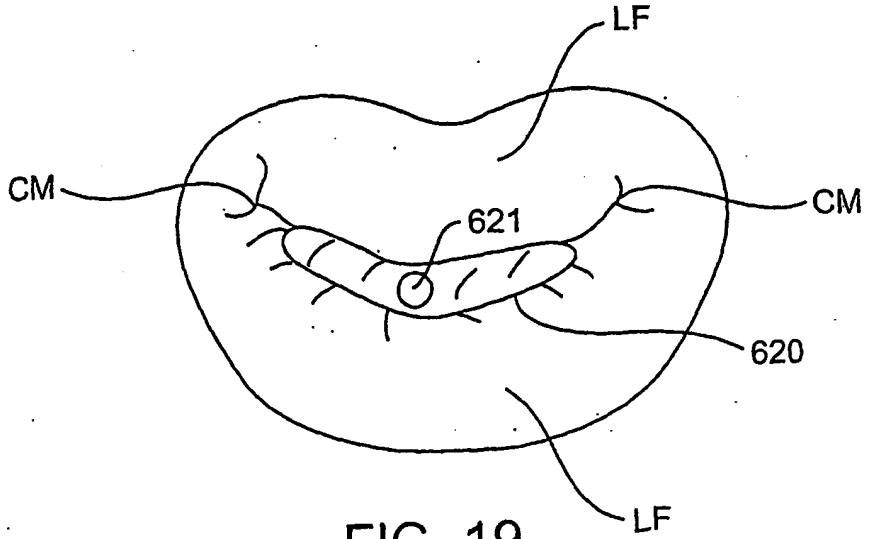


FIG. 19

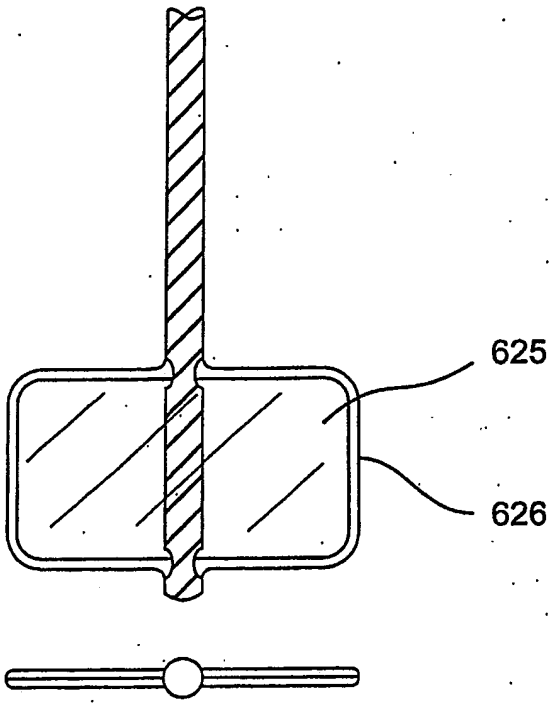


FIG. 20

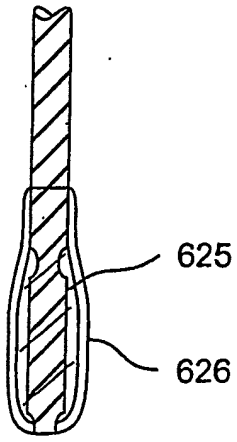


FIG. 21A

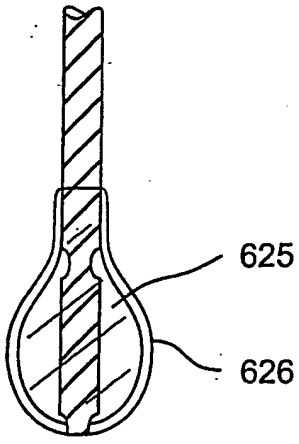


FIG. 21B

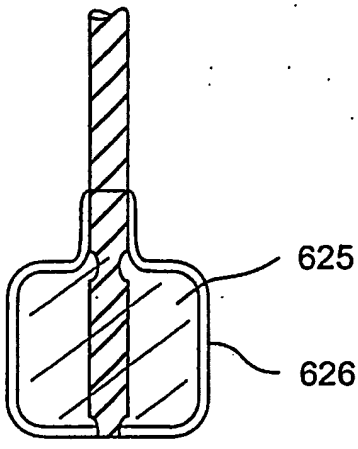


FIG. 21C

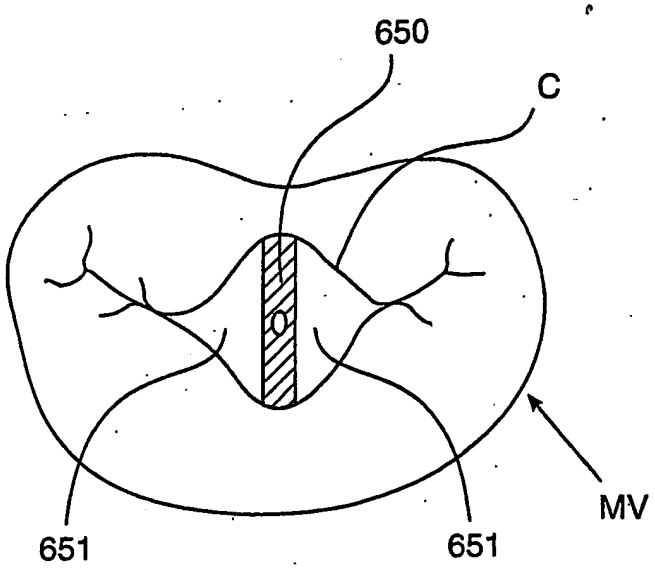


FIG. 22A

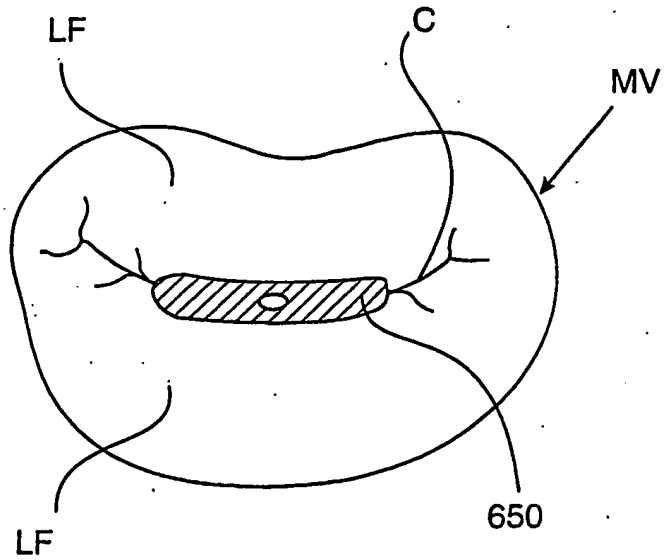


FIG. 22B

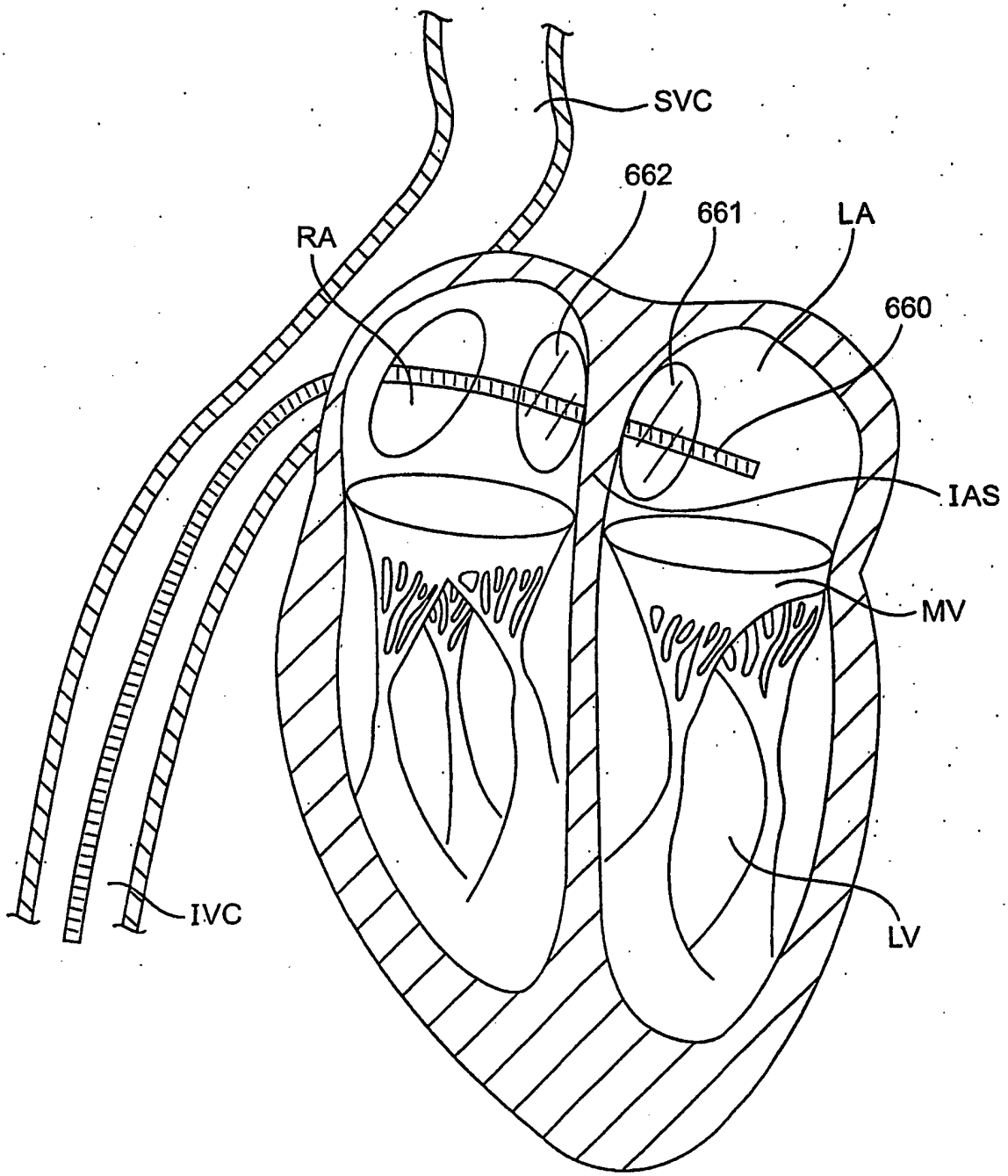


FIG. 23

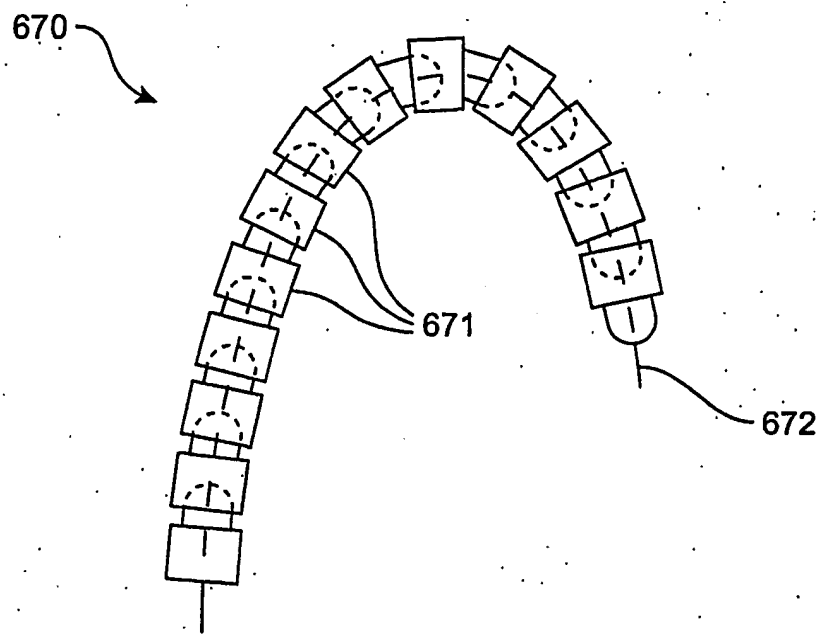


FIG. 24

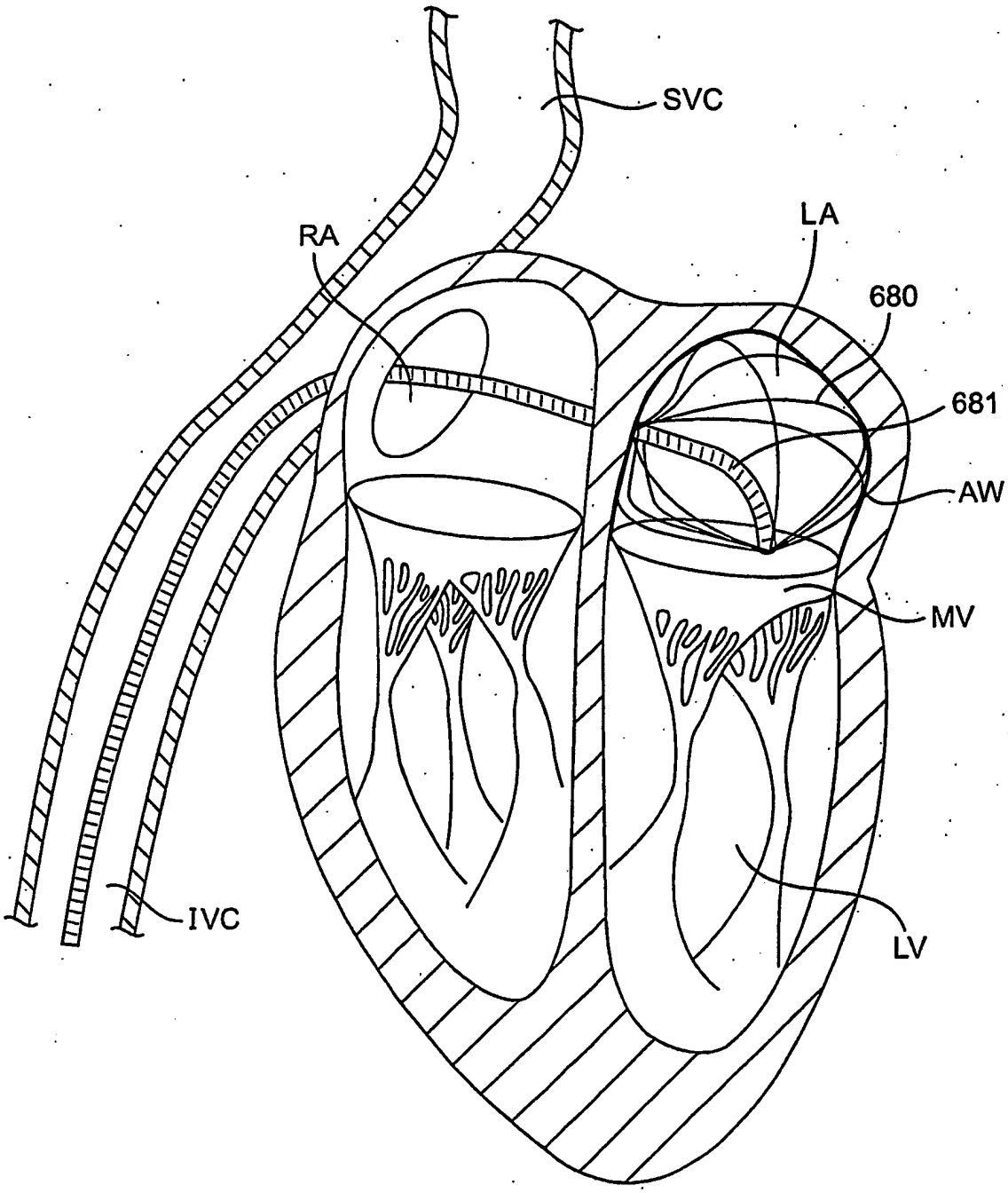


FIG. 25

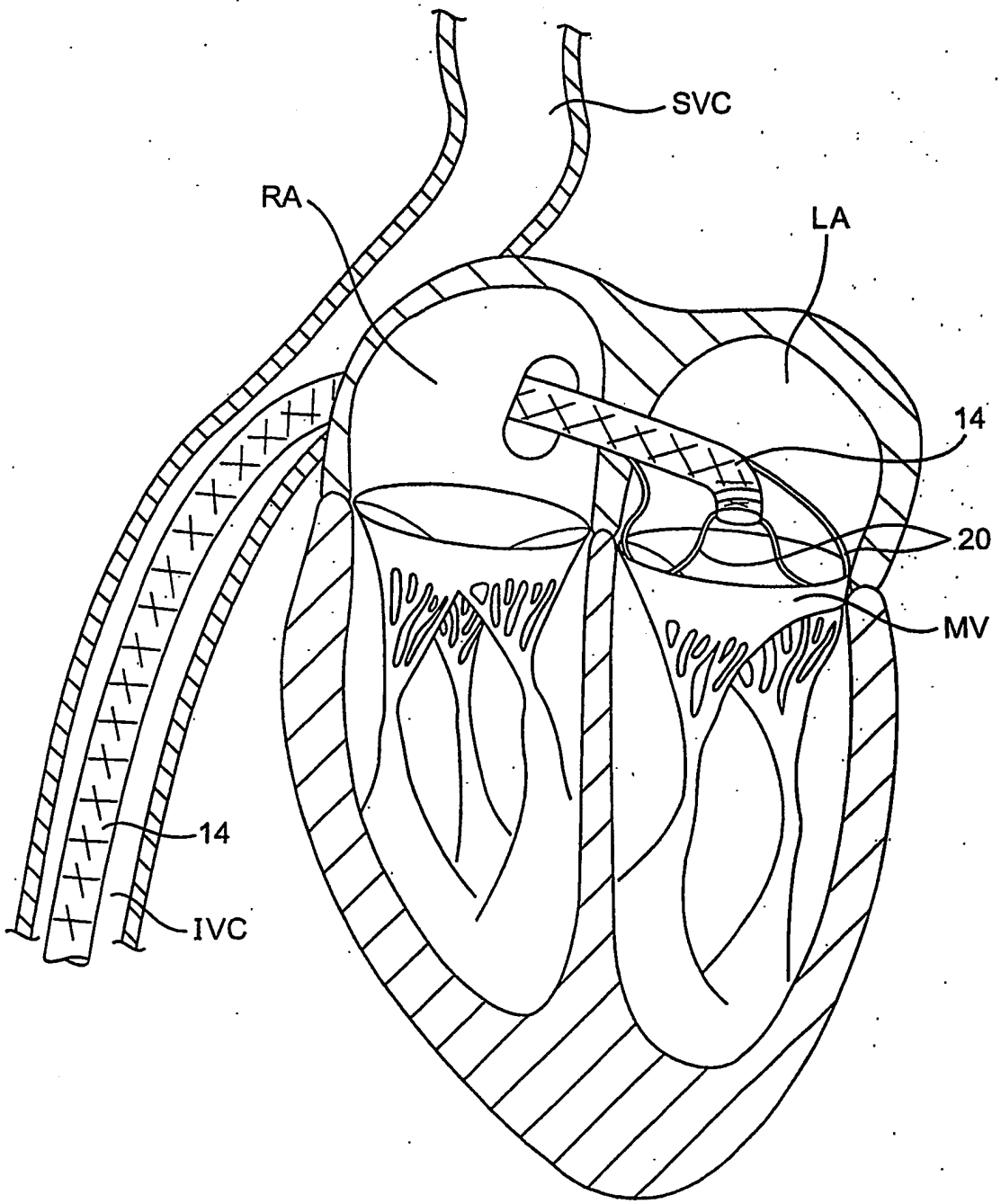


FIG. 26

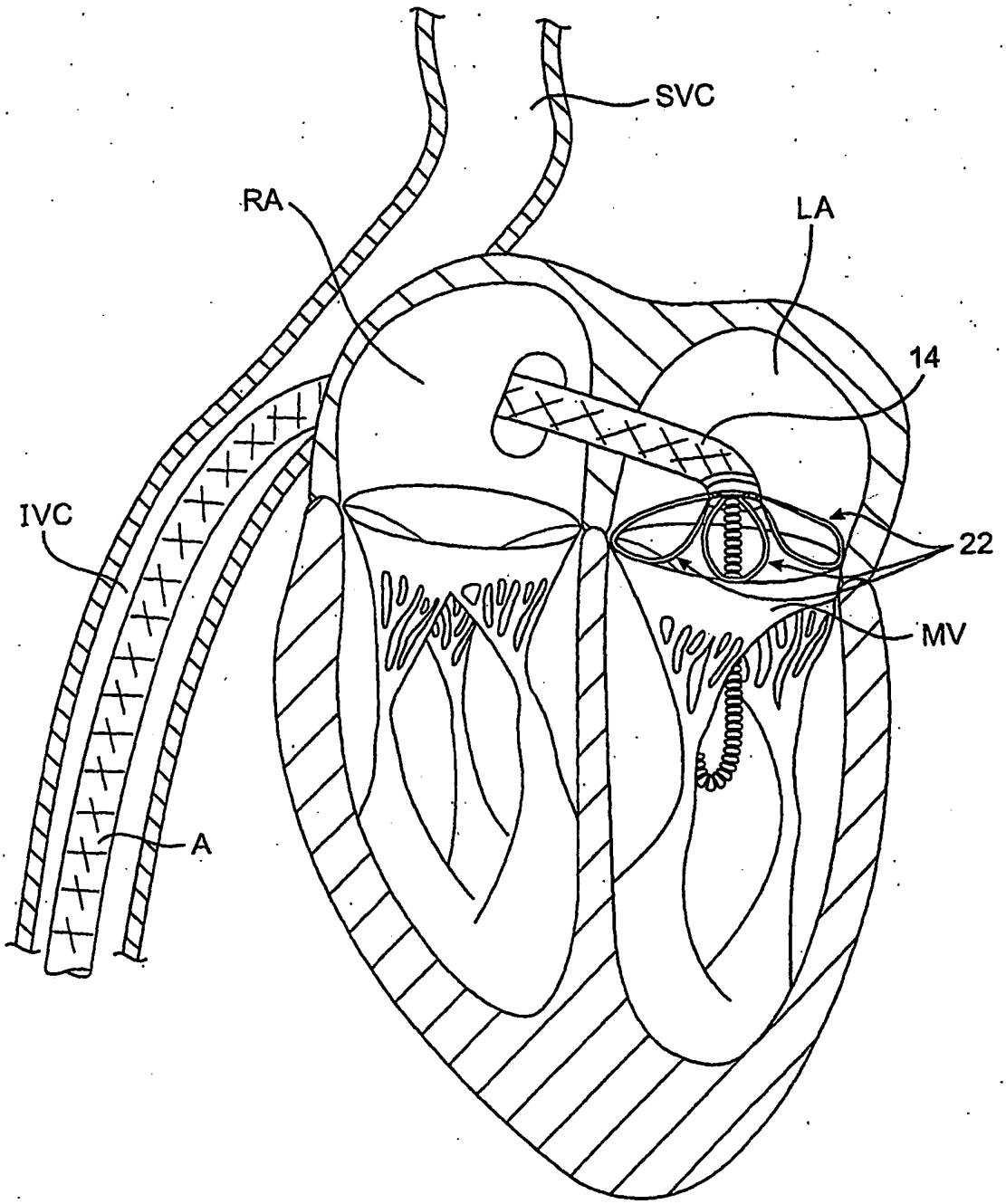


FIG. 27

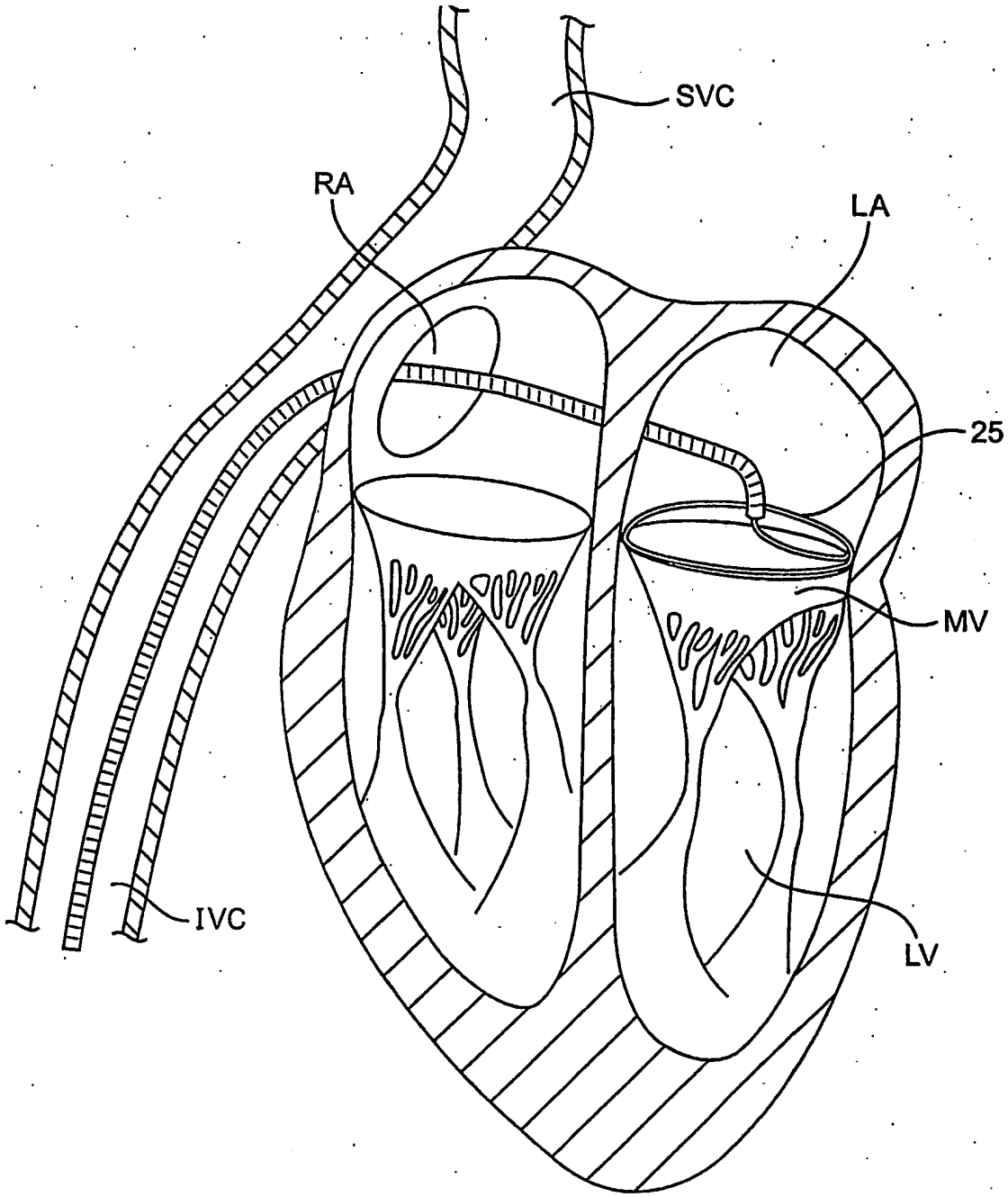


FIG. 28

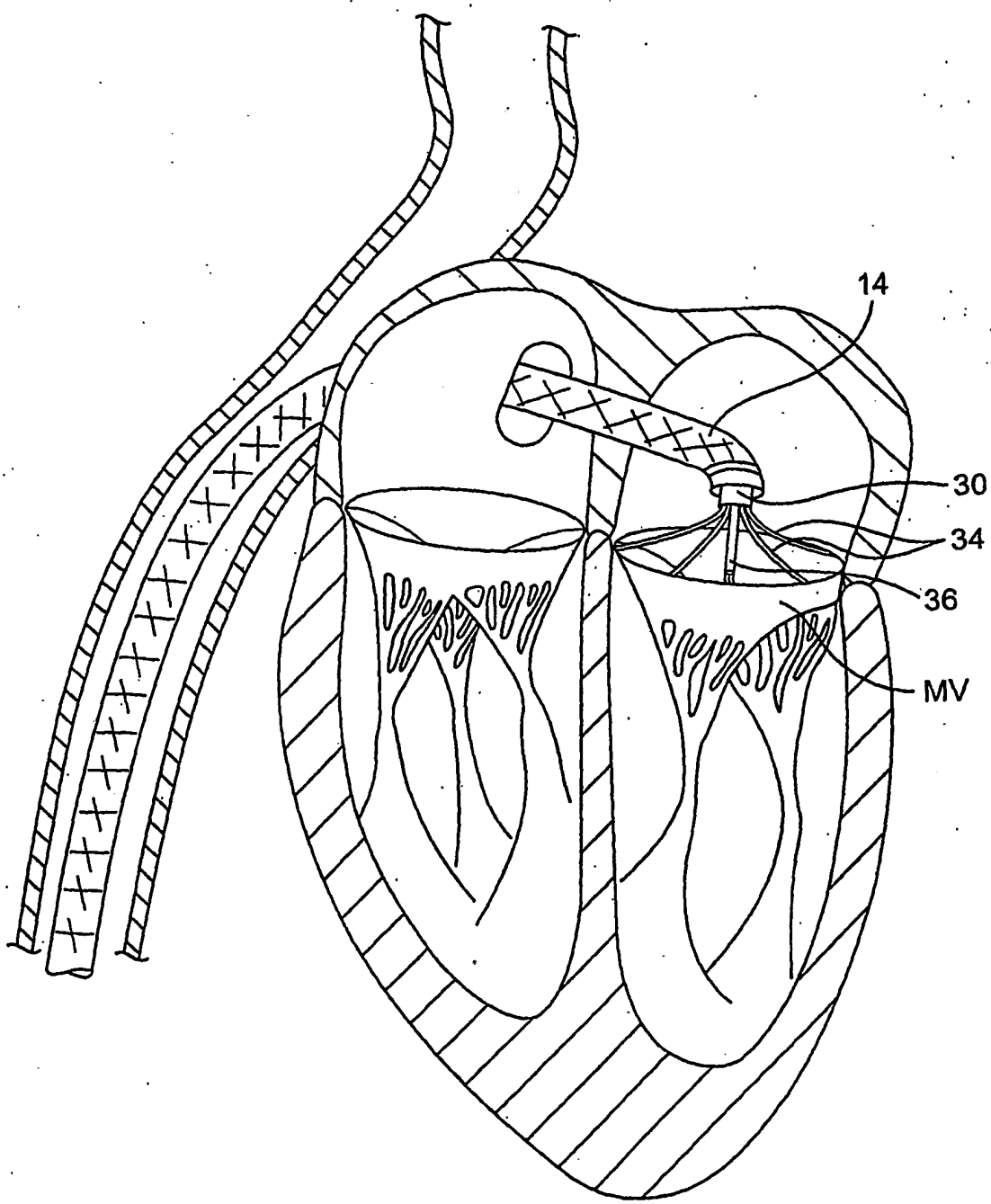


FIG. 29

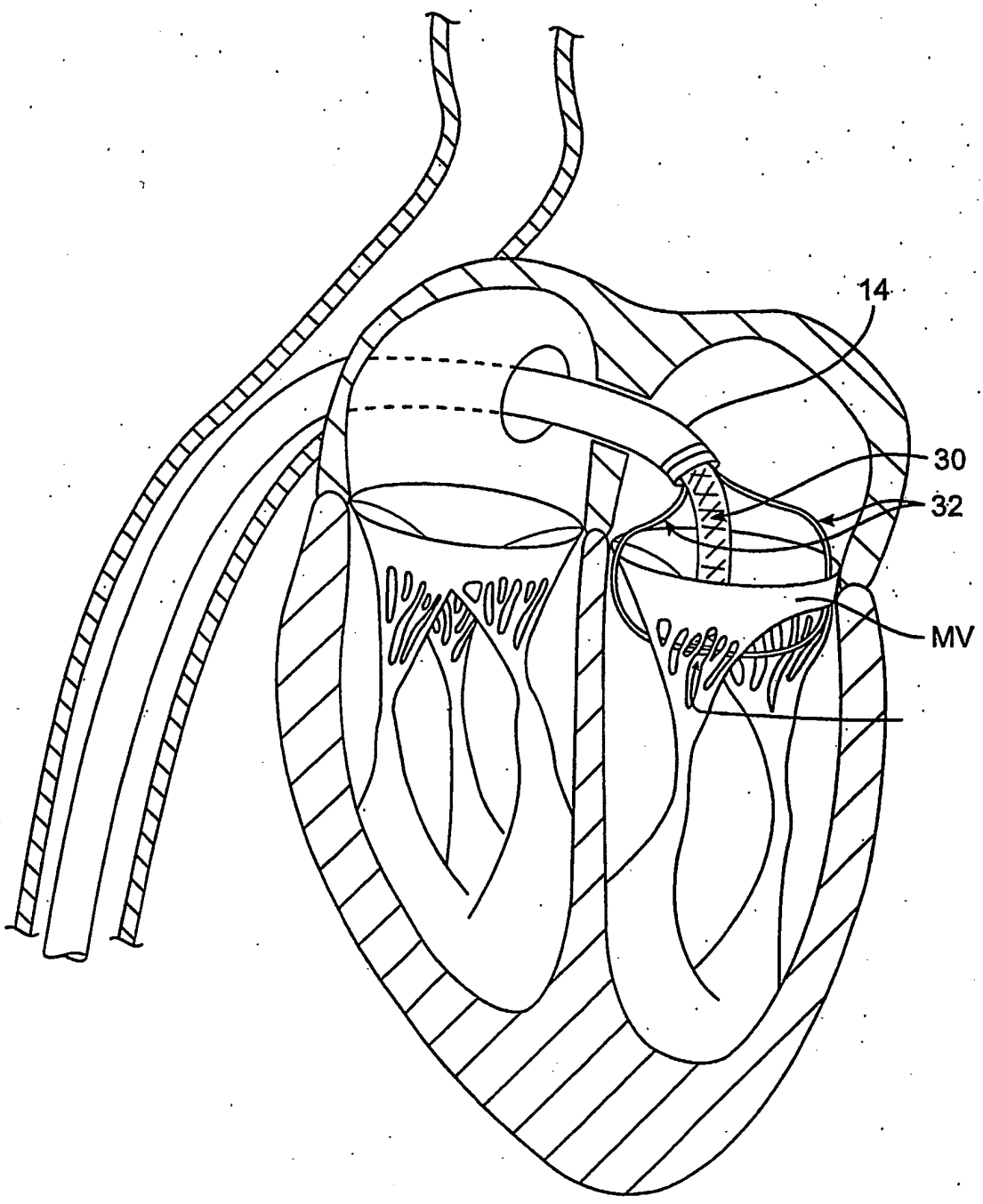


FIG. 30

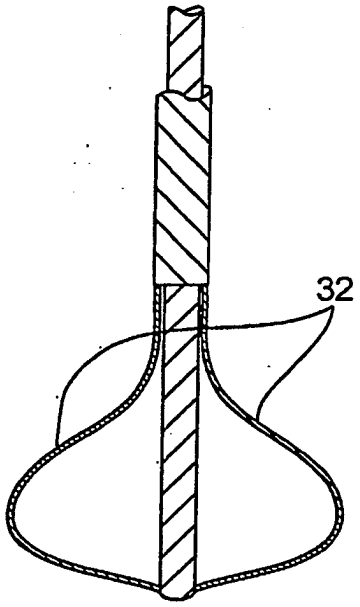


FIG. 31A

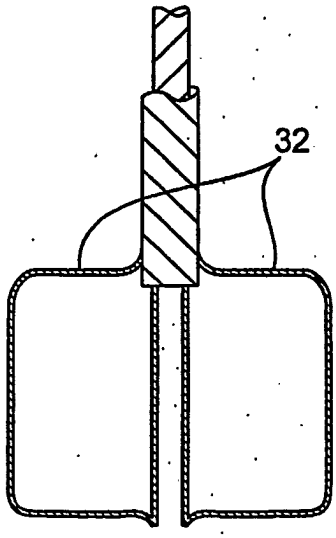


FIG. 31B

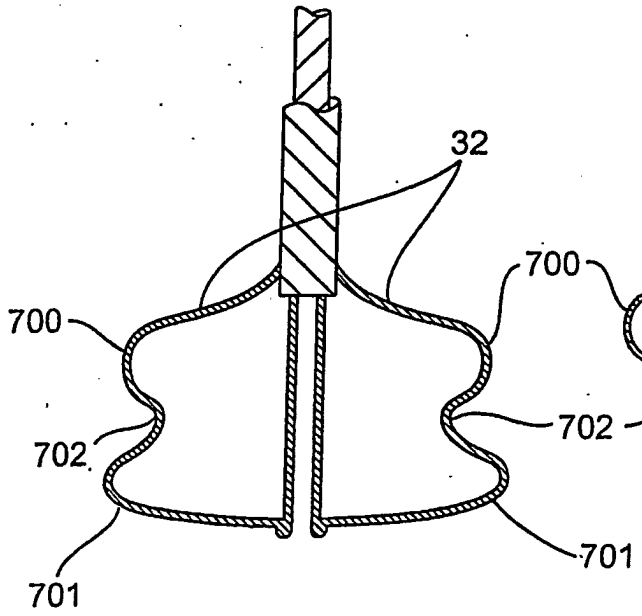


FIG. 31C

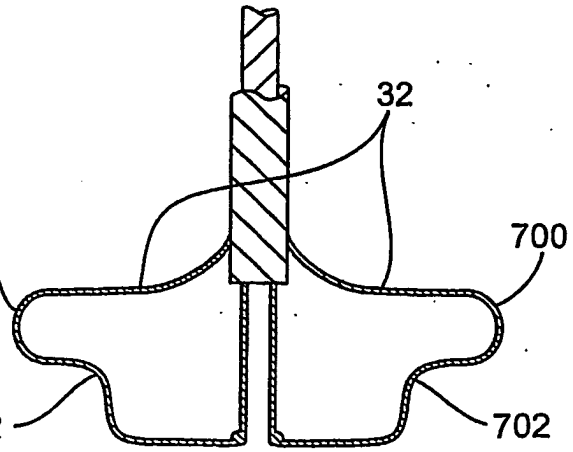


FIG. 31D

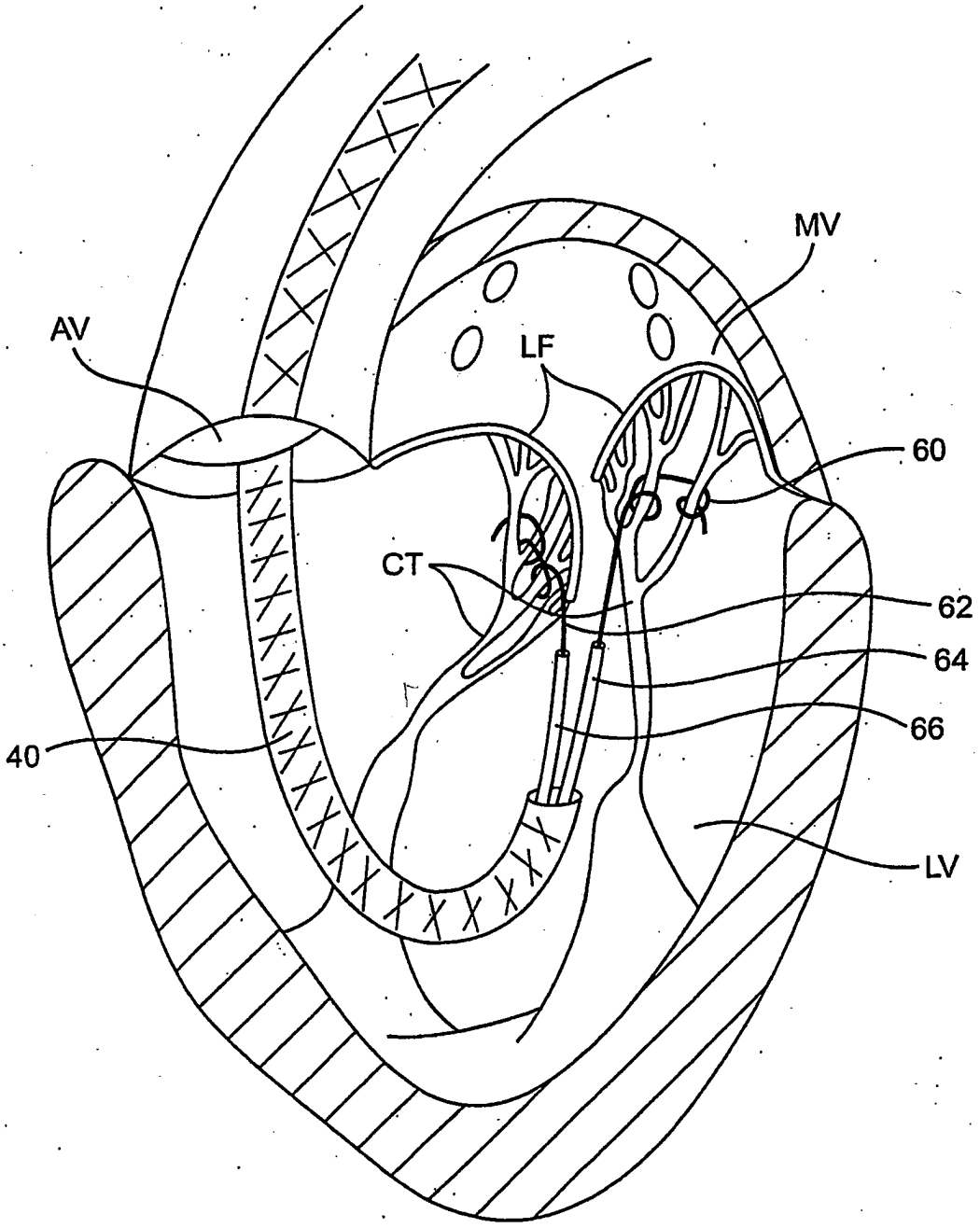


FIG. 32A

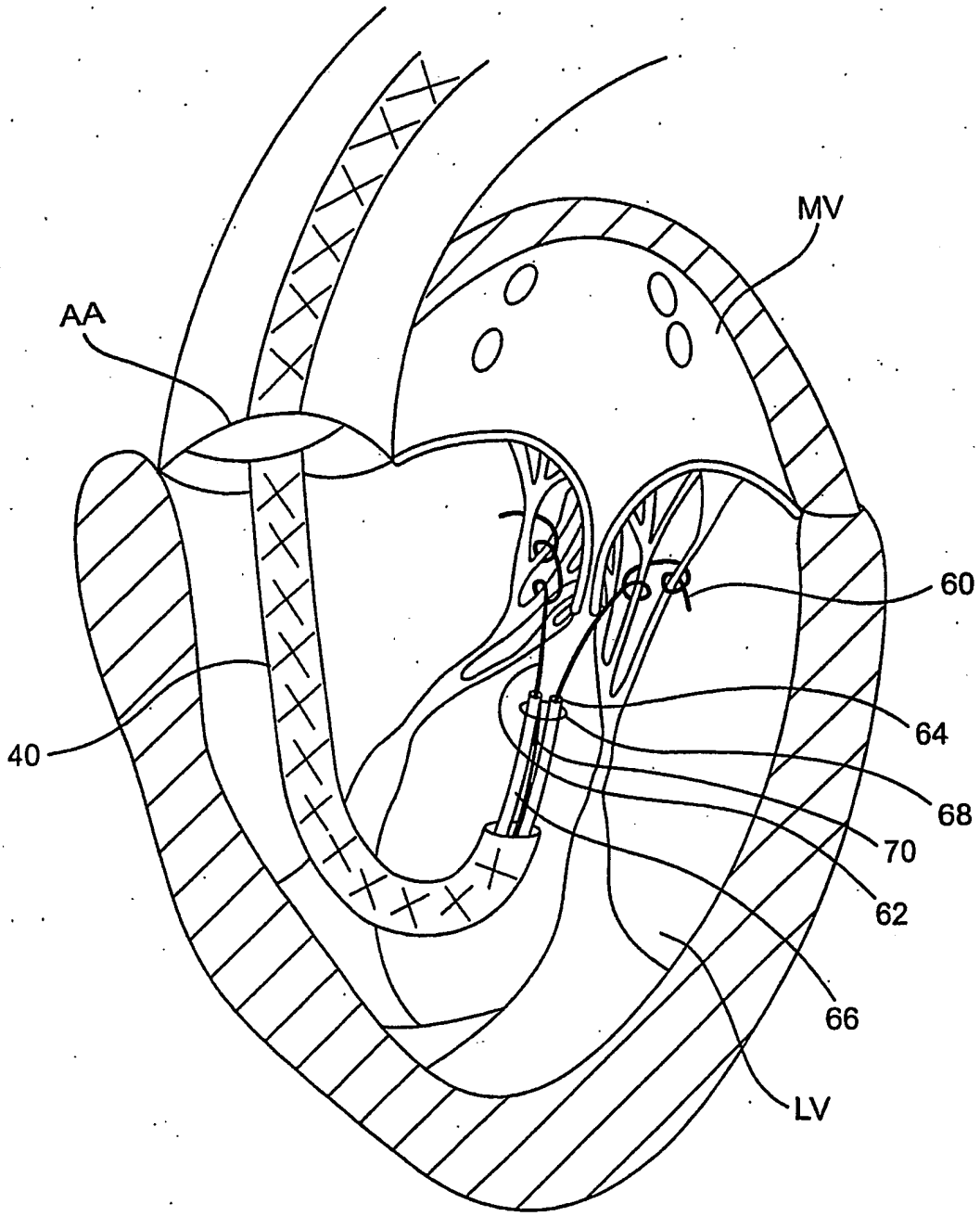


FIG. 32B

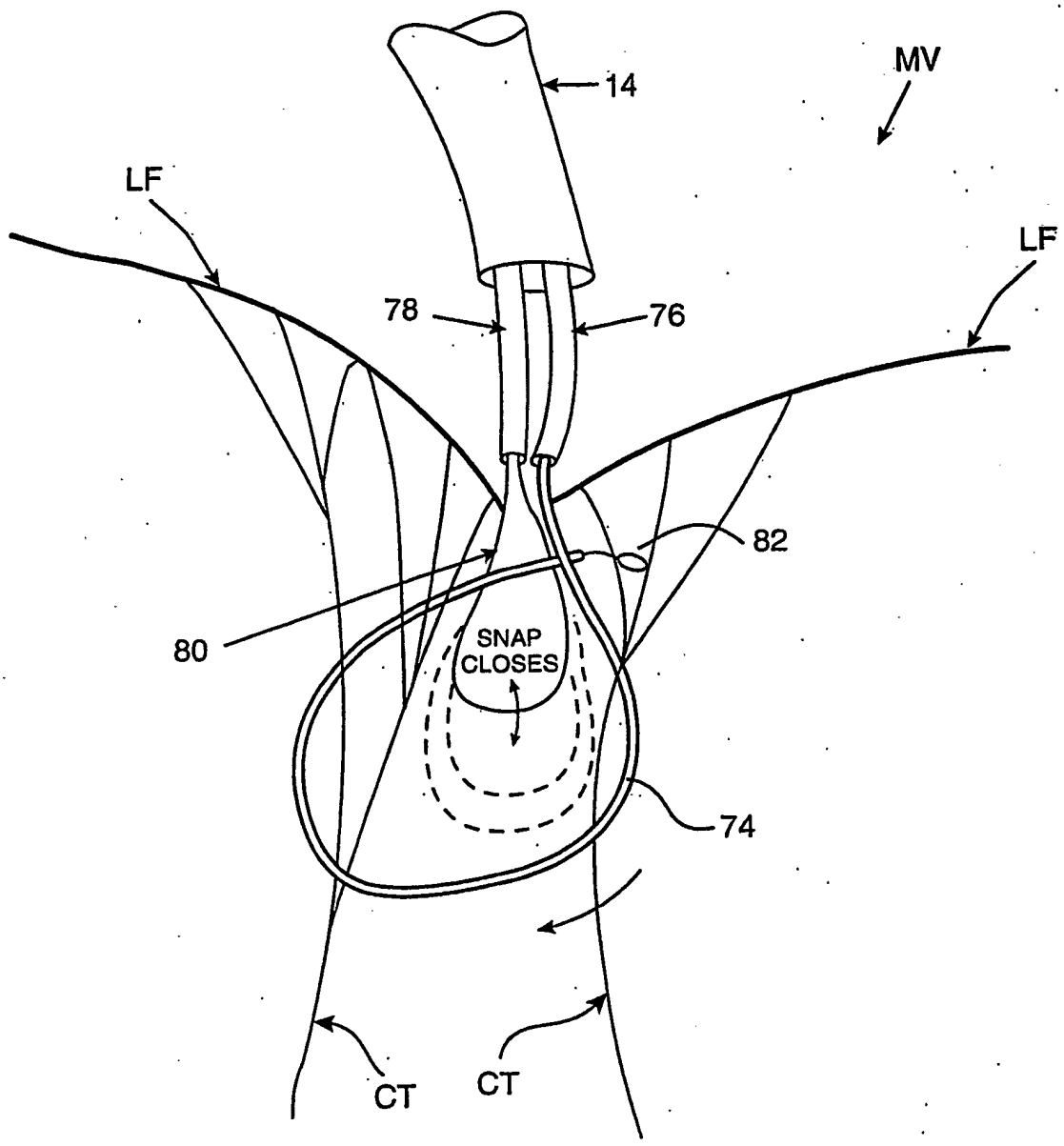


FIG. 33A

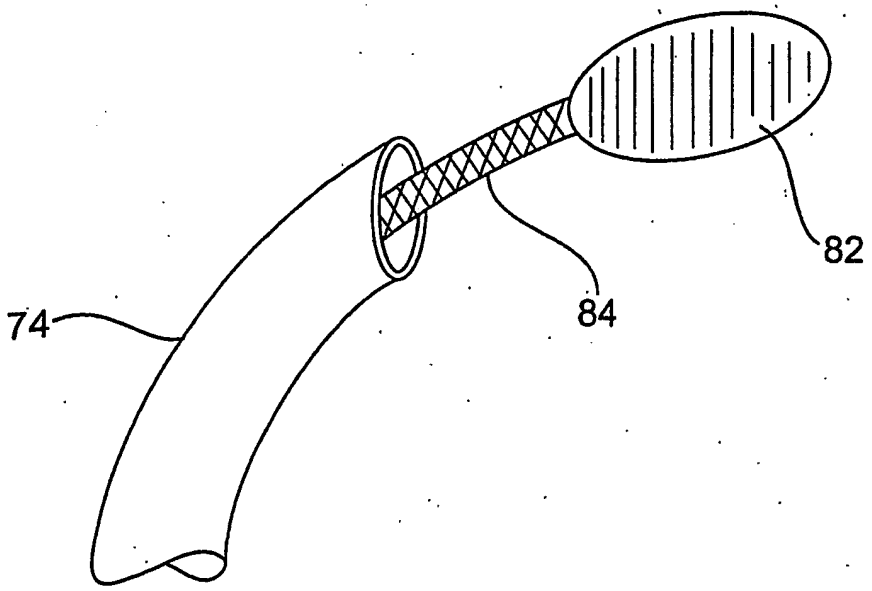


FIG. 33B

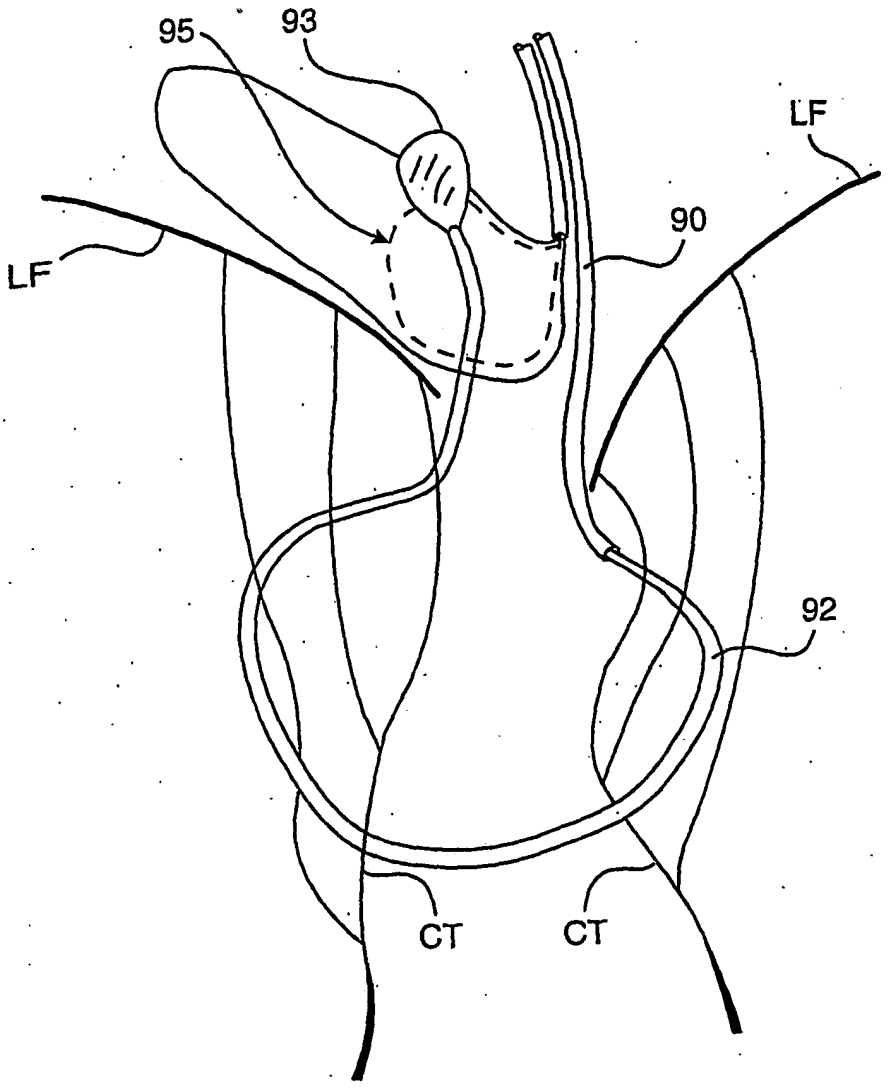


FIG. 34

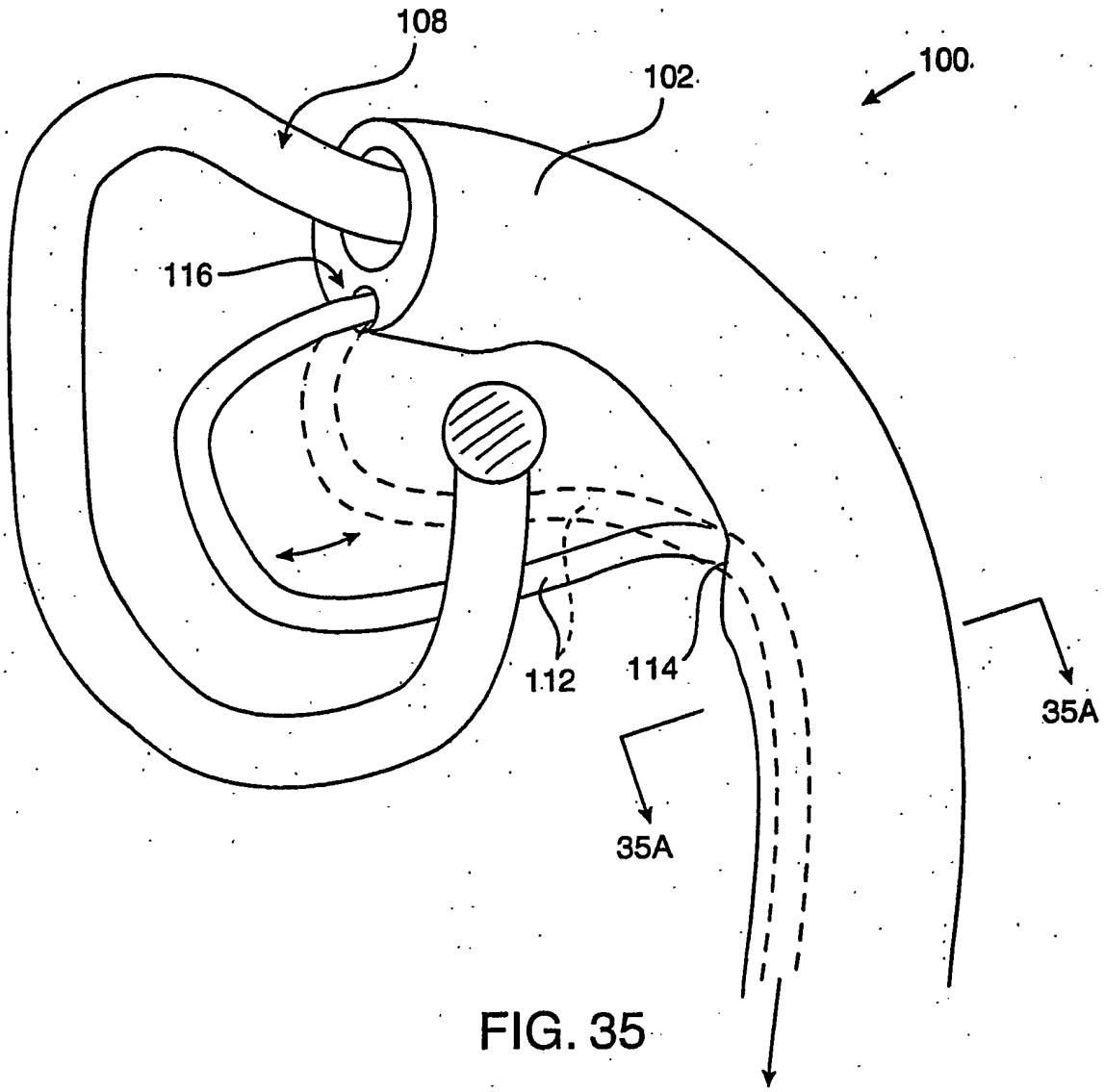


FIG. 35

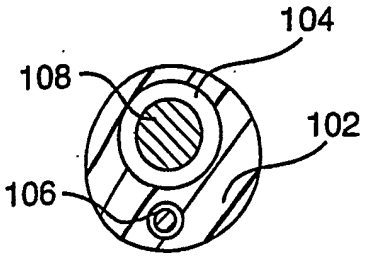


FIG. 35A

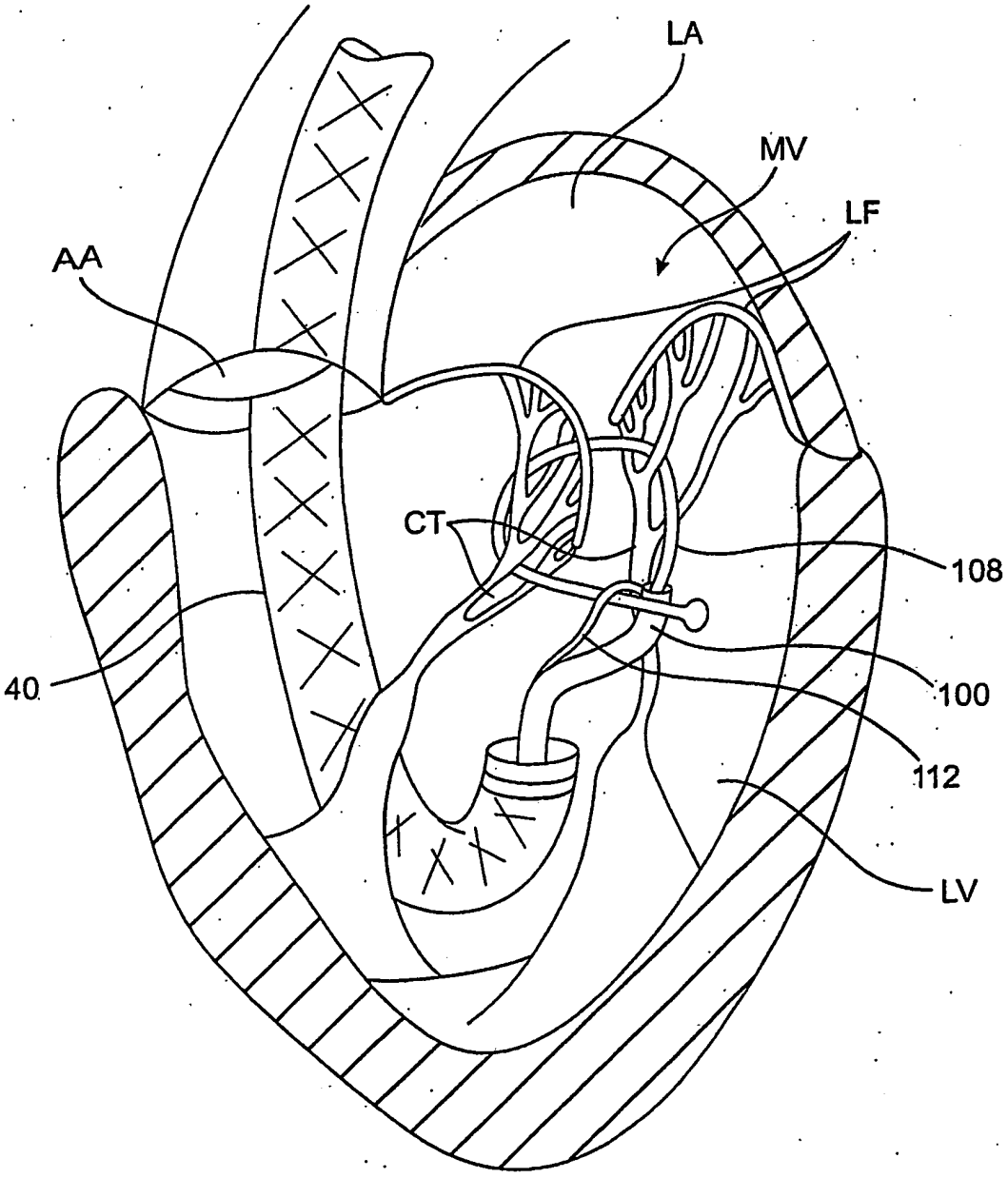


FIG. 36A

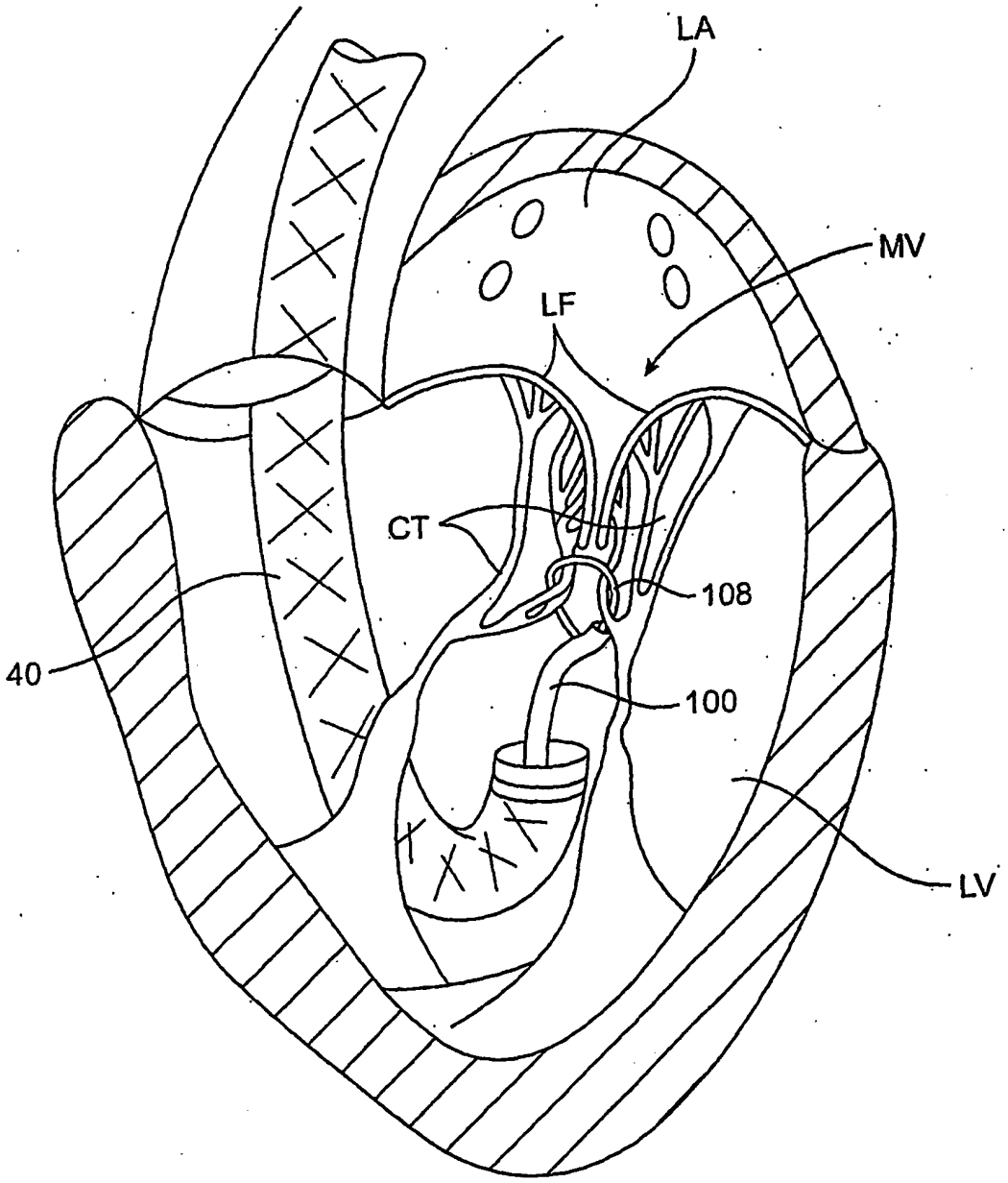


FIG. 36B

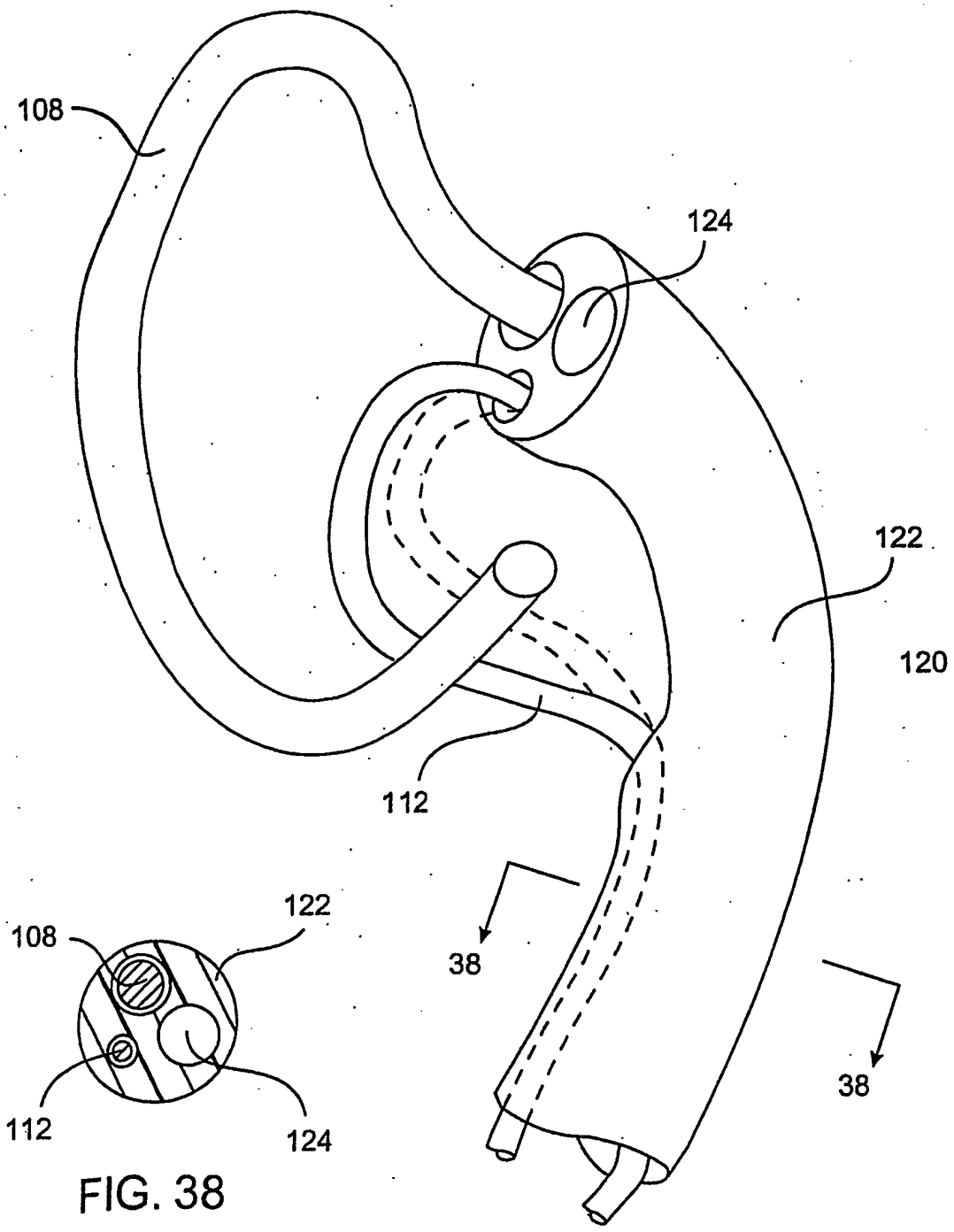


FIG. 37

FIG. 38

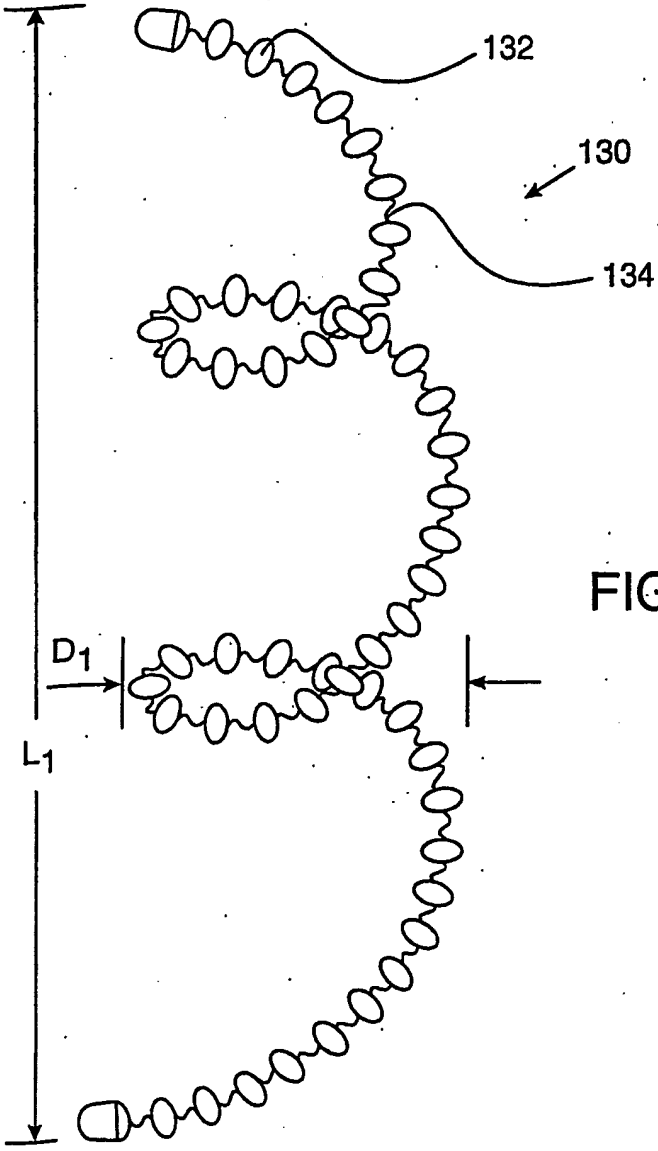


FIG. 39A

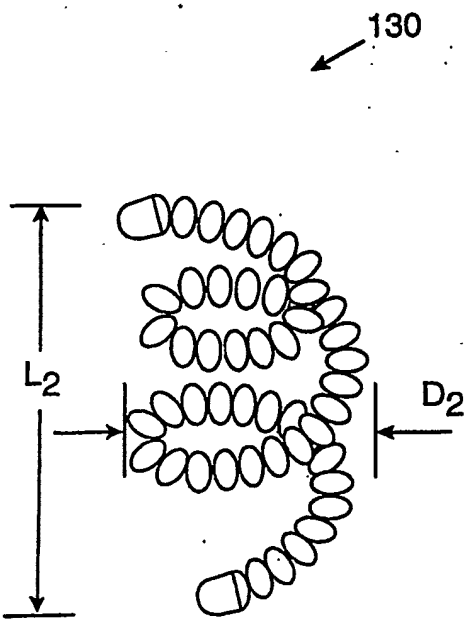


FIG. 39B

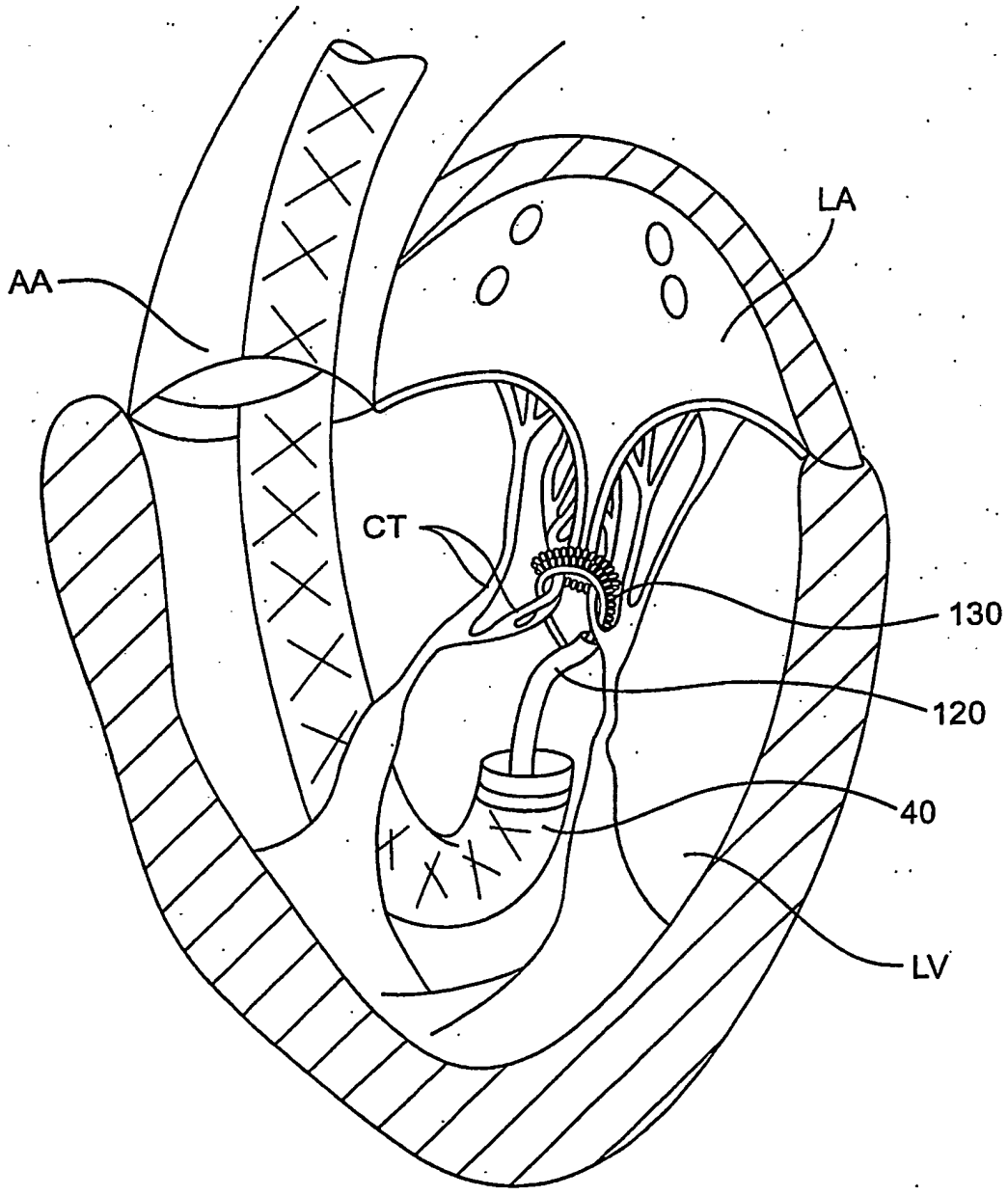


FIG. 40

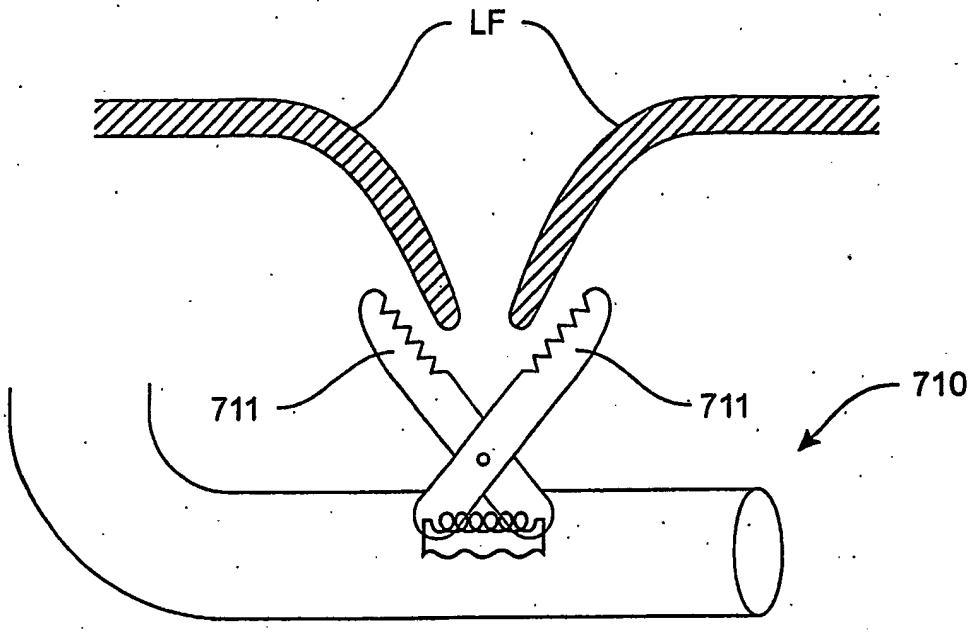


FIG. 41A

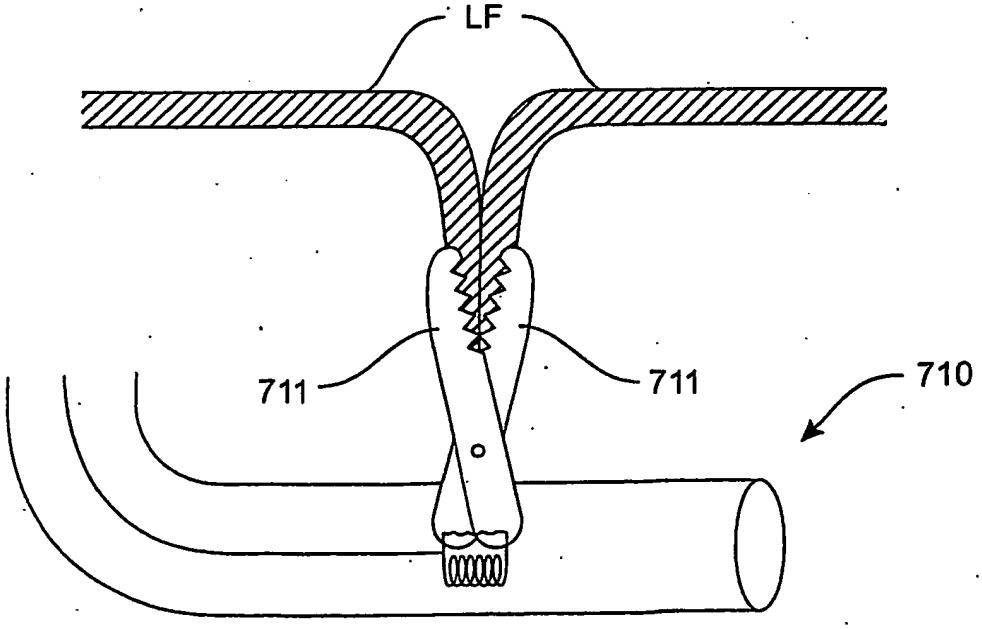


FIG. 41B

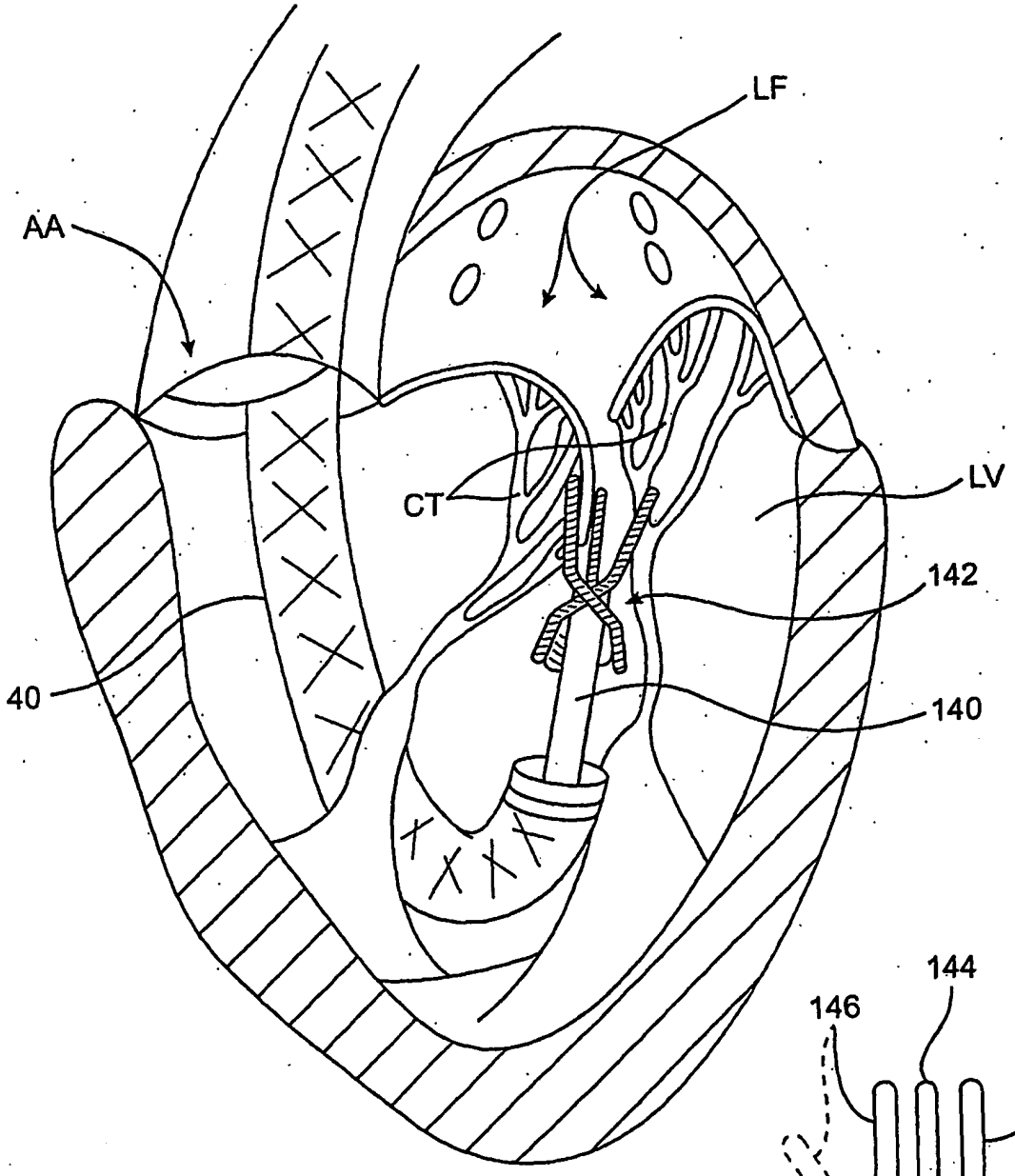


FIG. 42A

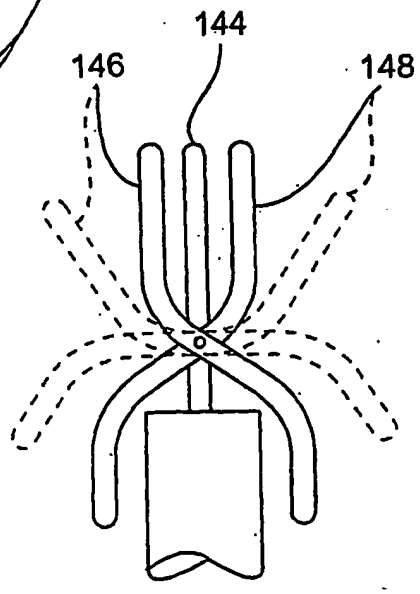


FIG. 42B

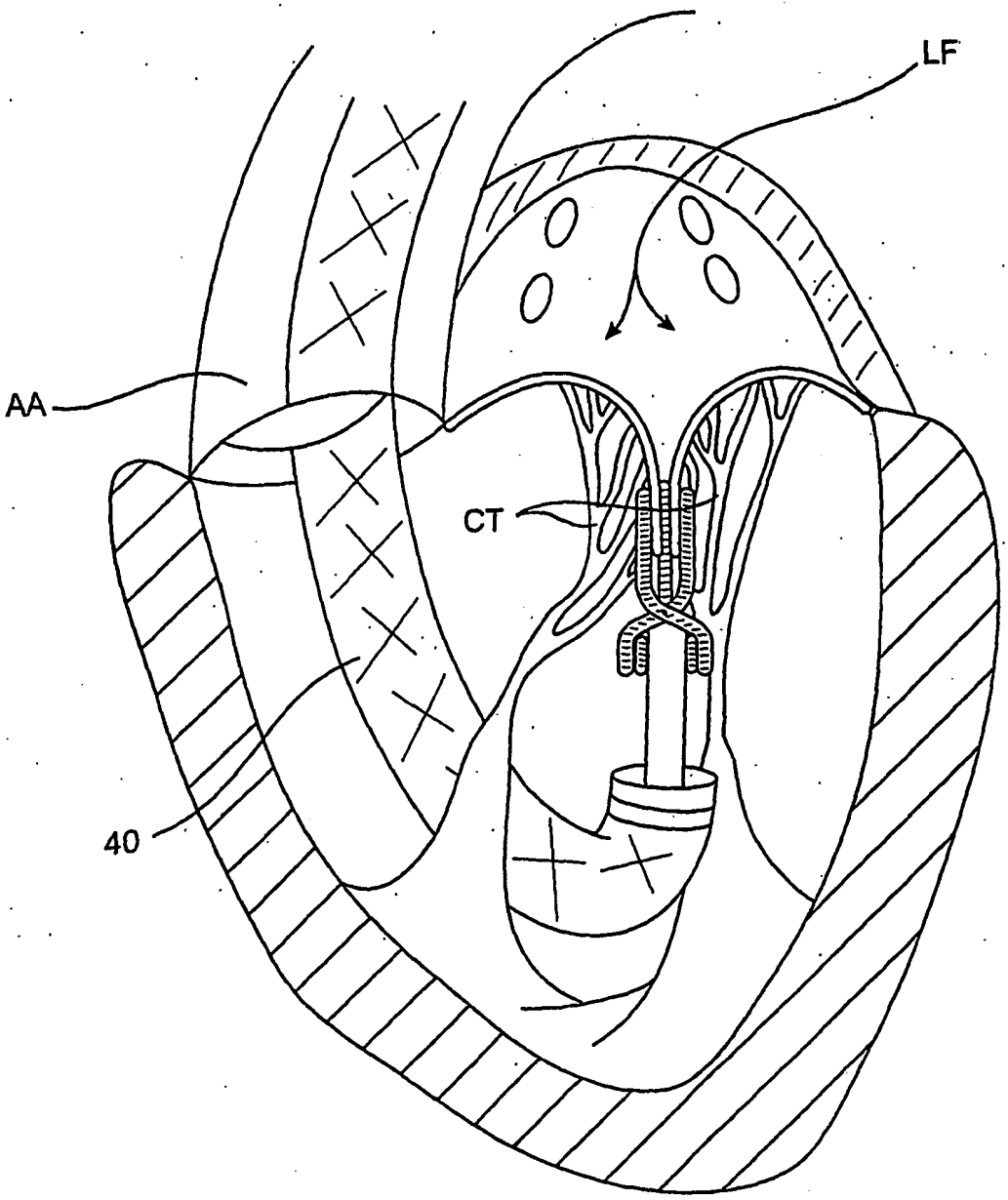


FIG. 43

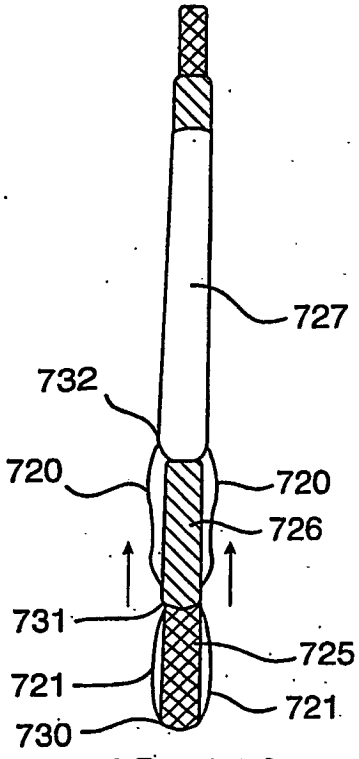


FIG. 44A

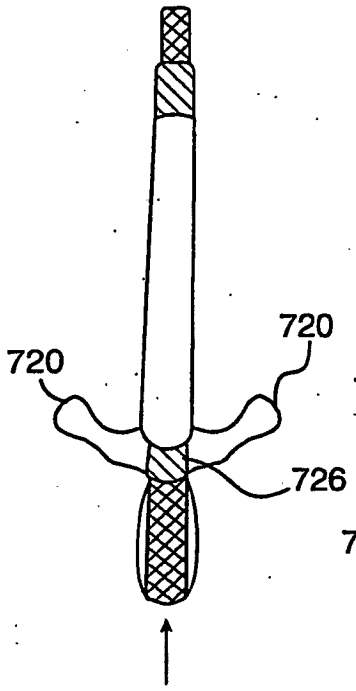


FIG. 44B

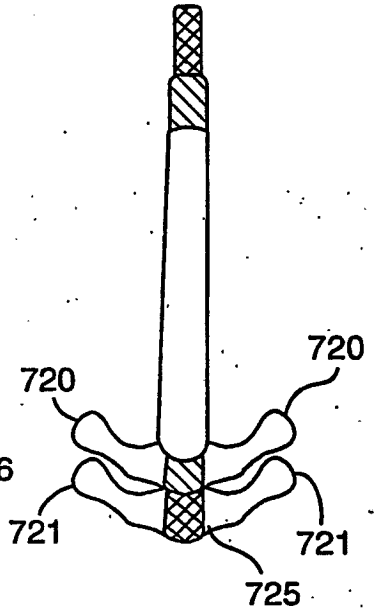


FIG. 44C

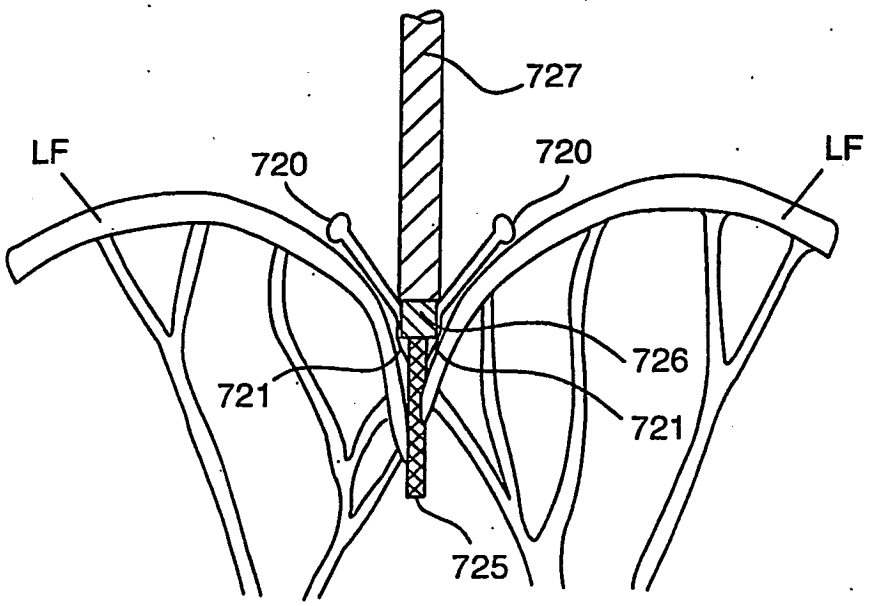


FIG. 44D

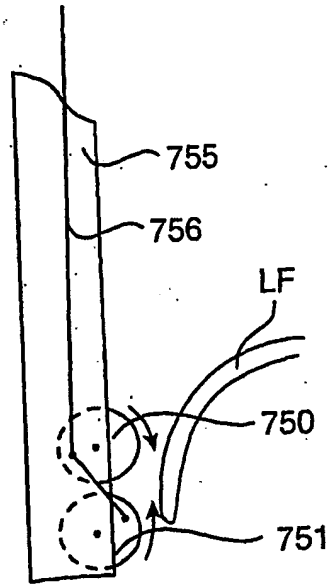


FIG. 45A

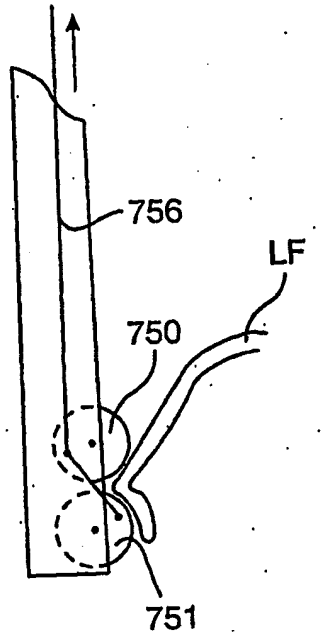


FIG. 45B

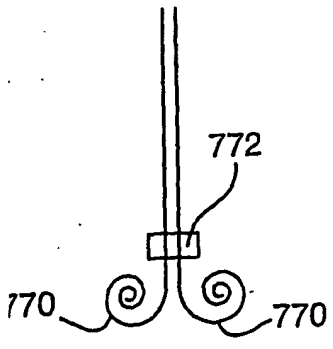


FIG. 46A

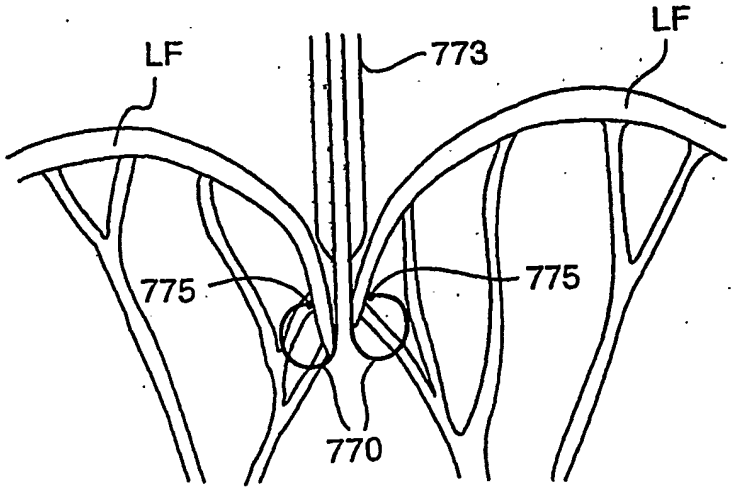


FIG. 46B

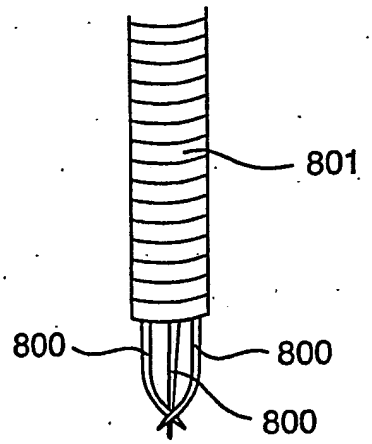


FIG. 47A

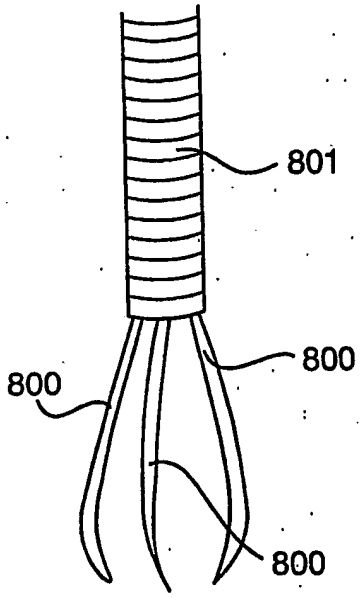


FIG. 47B

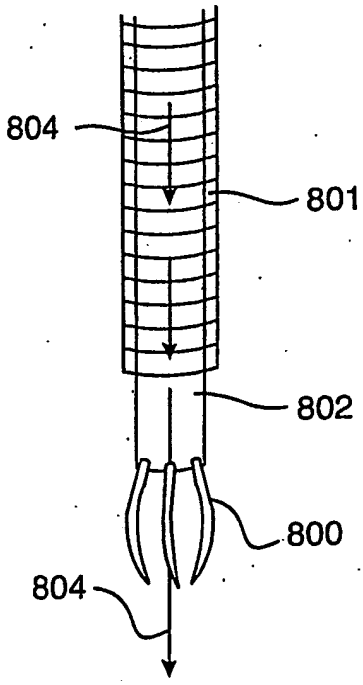


FIG. 47C

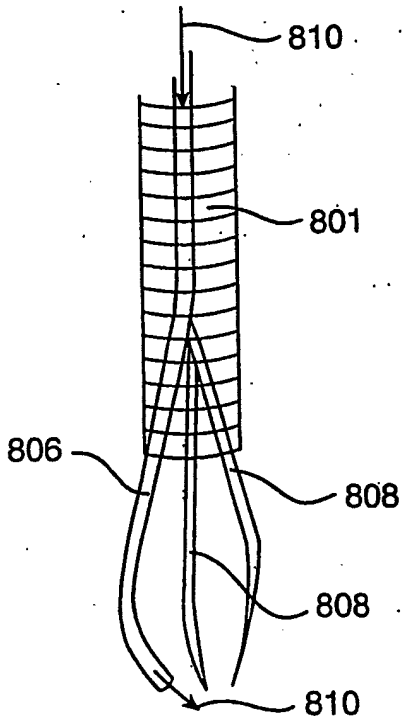


FIG. 47D

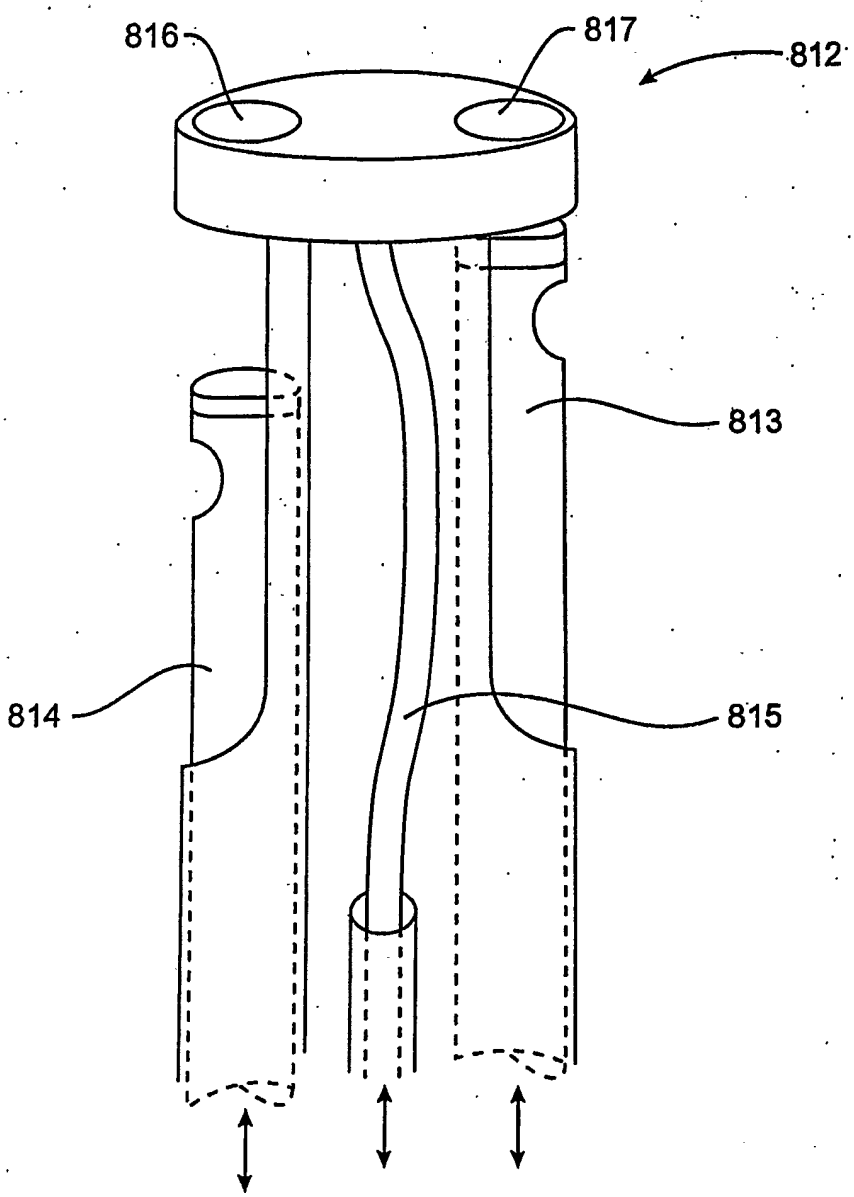


FIG. 48

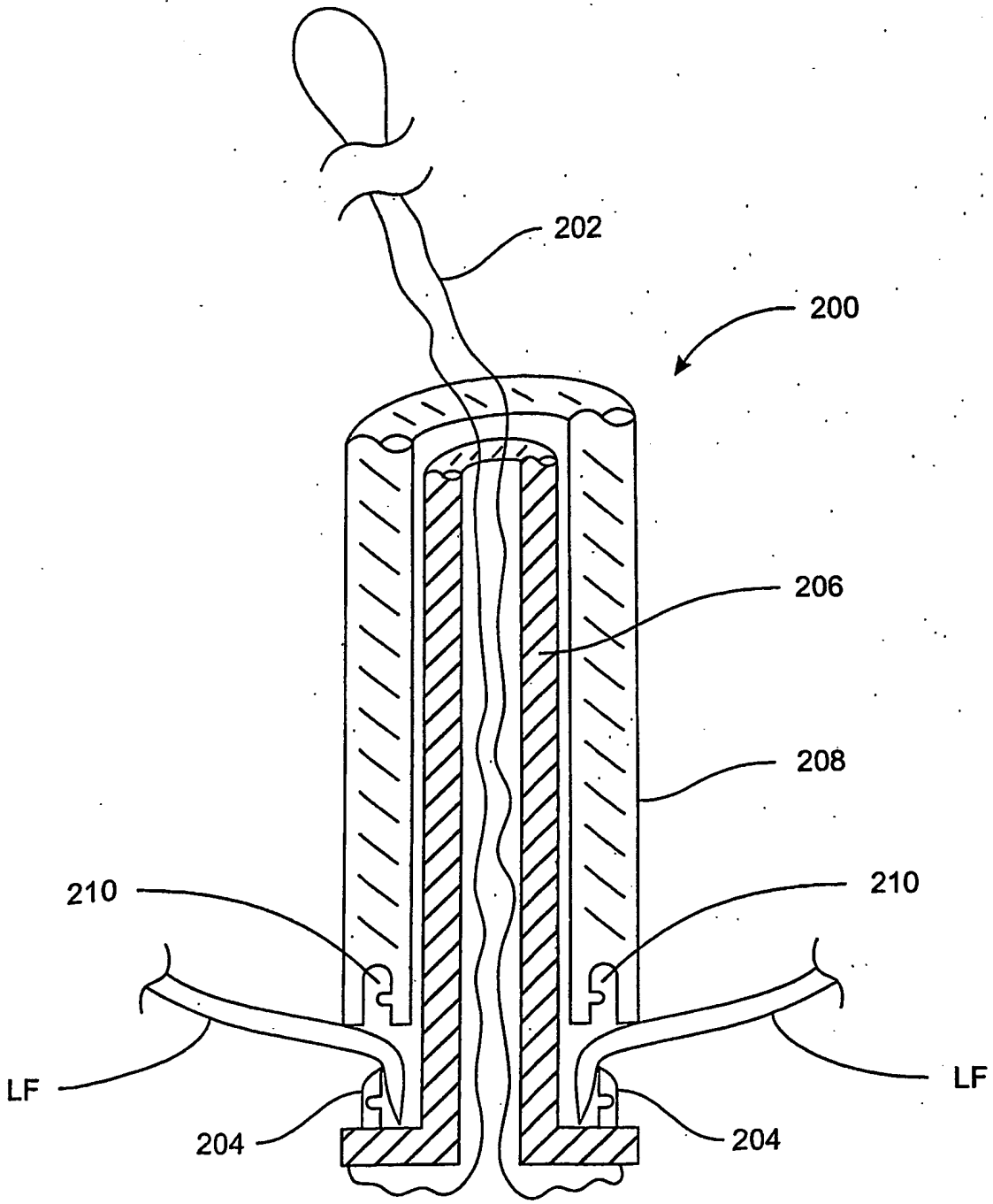


FIG. 49

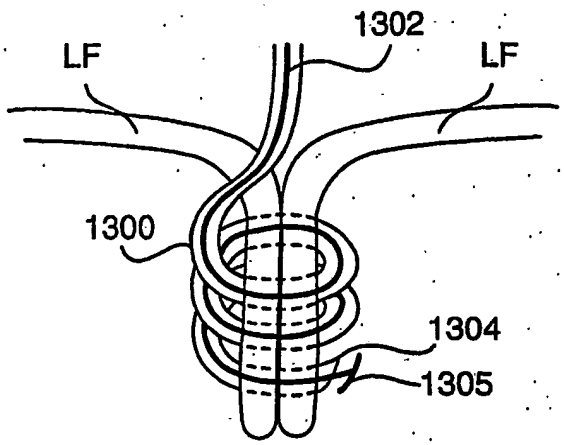


FIG. 49A

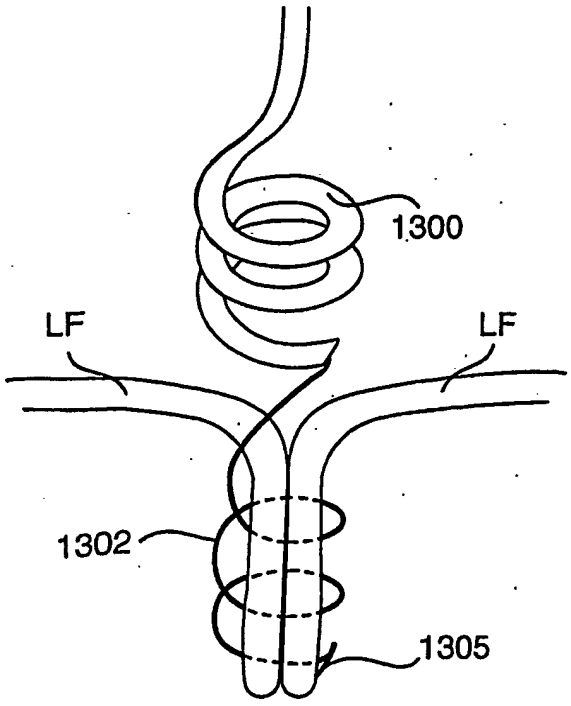


FIG. 49B

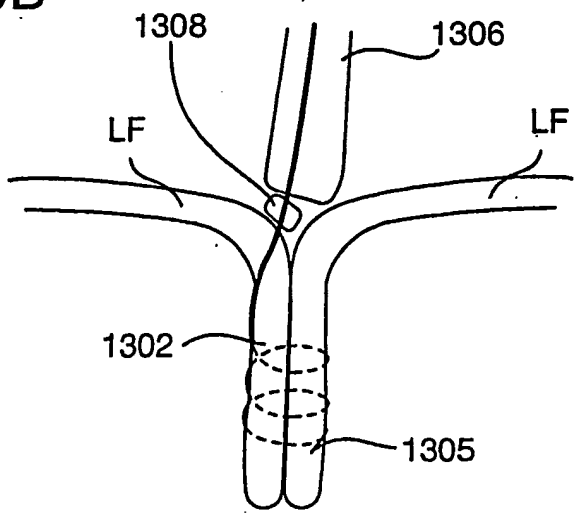


FIG. 49C

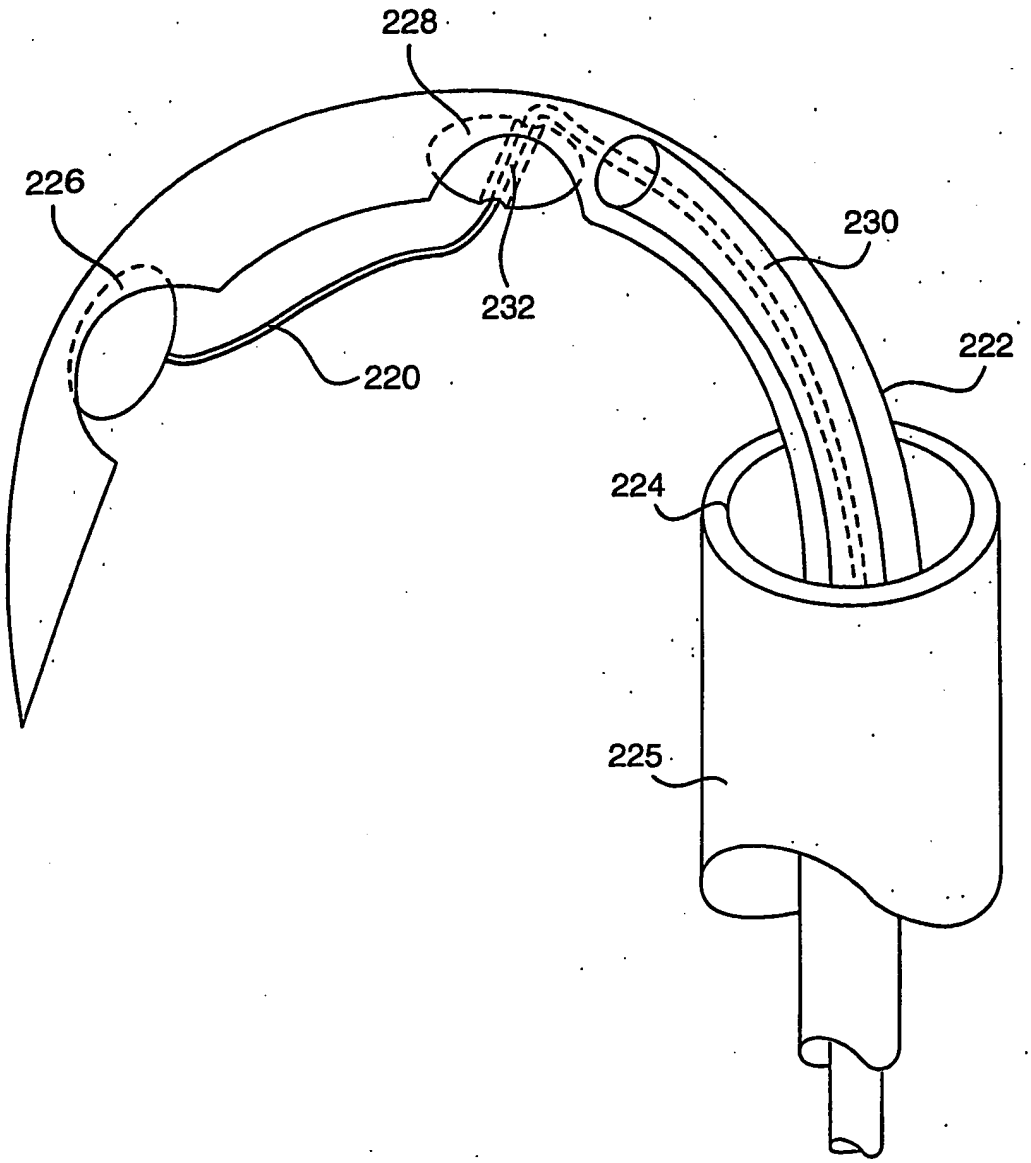


FIG. 50

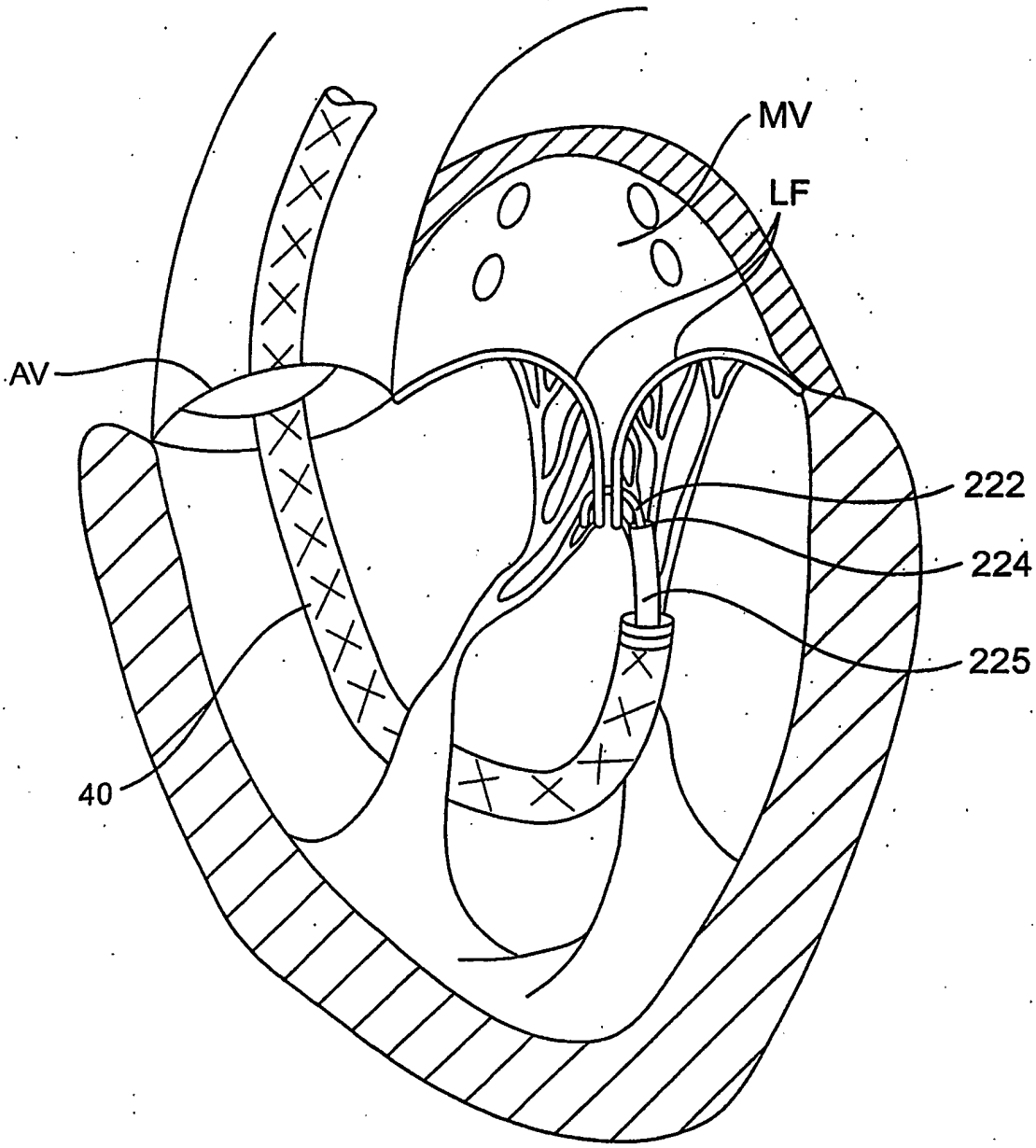


FIG. 51

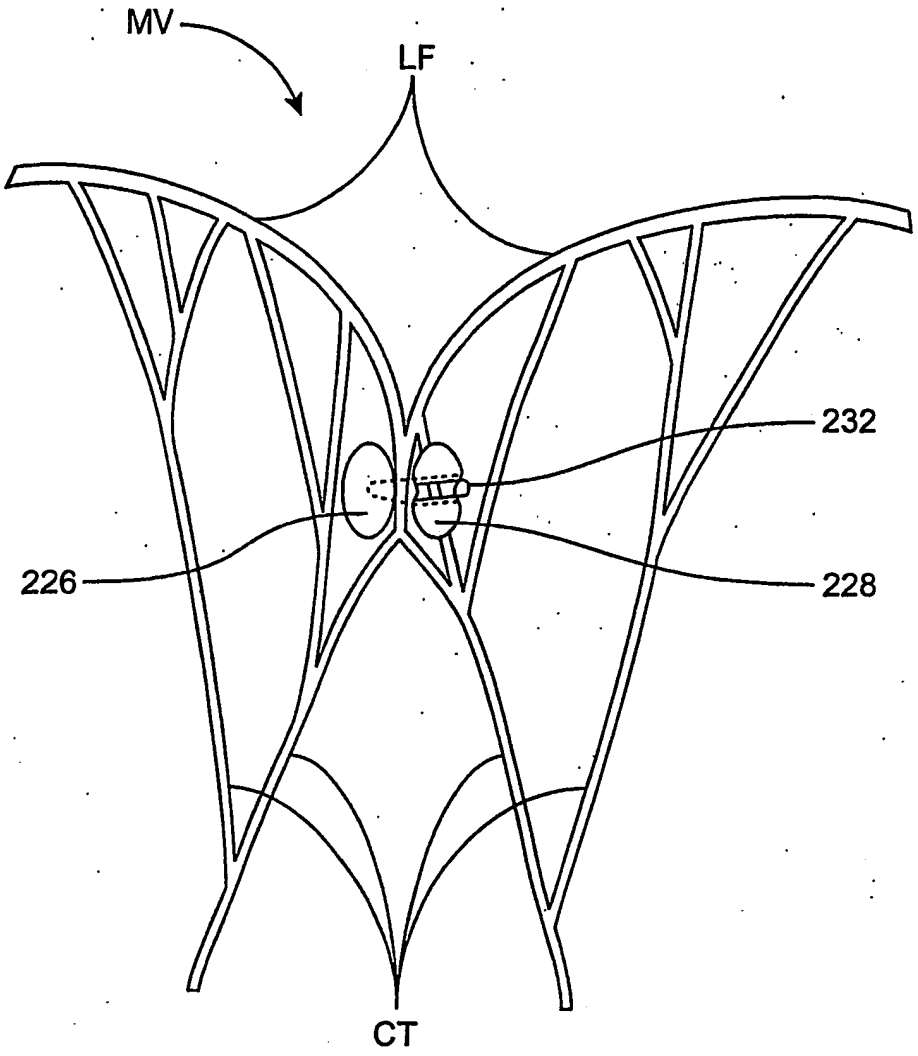


FIG. 52

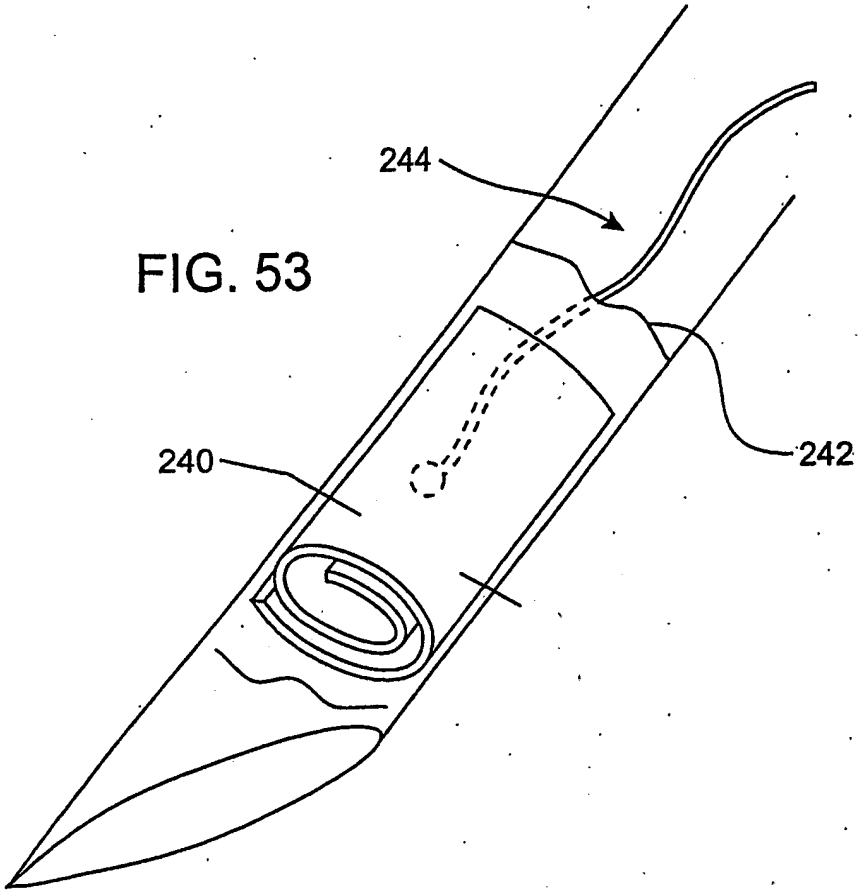


FIG. 53

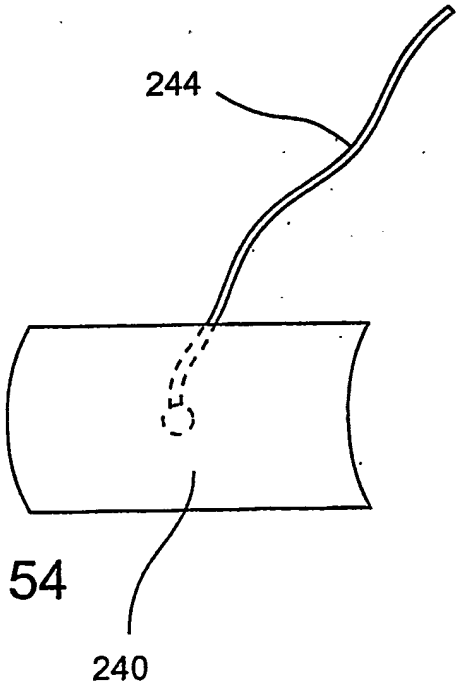


FIG. 54

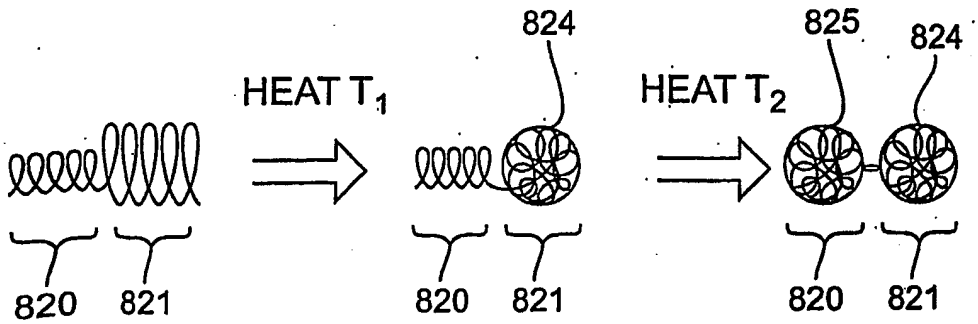


FIG. 55A

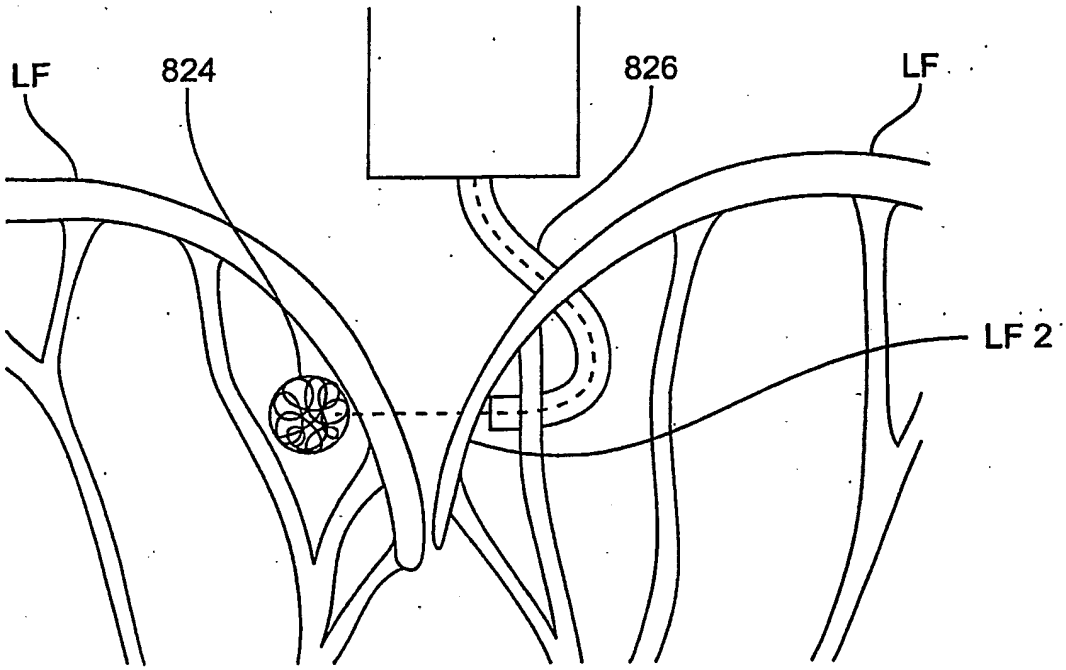


FIG. 55B

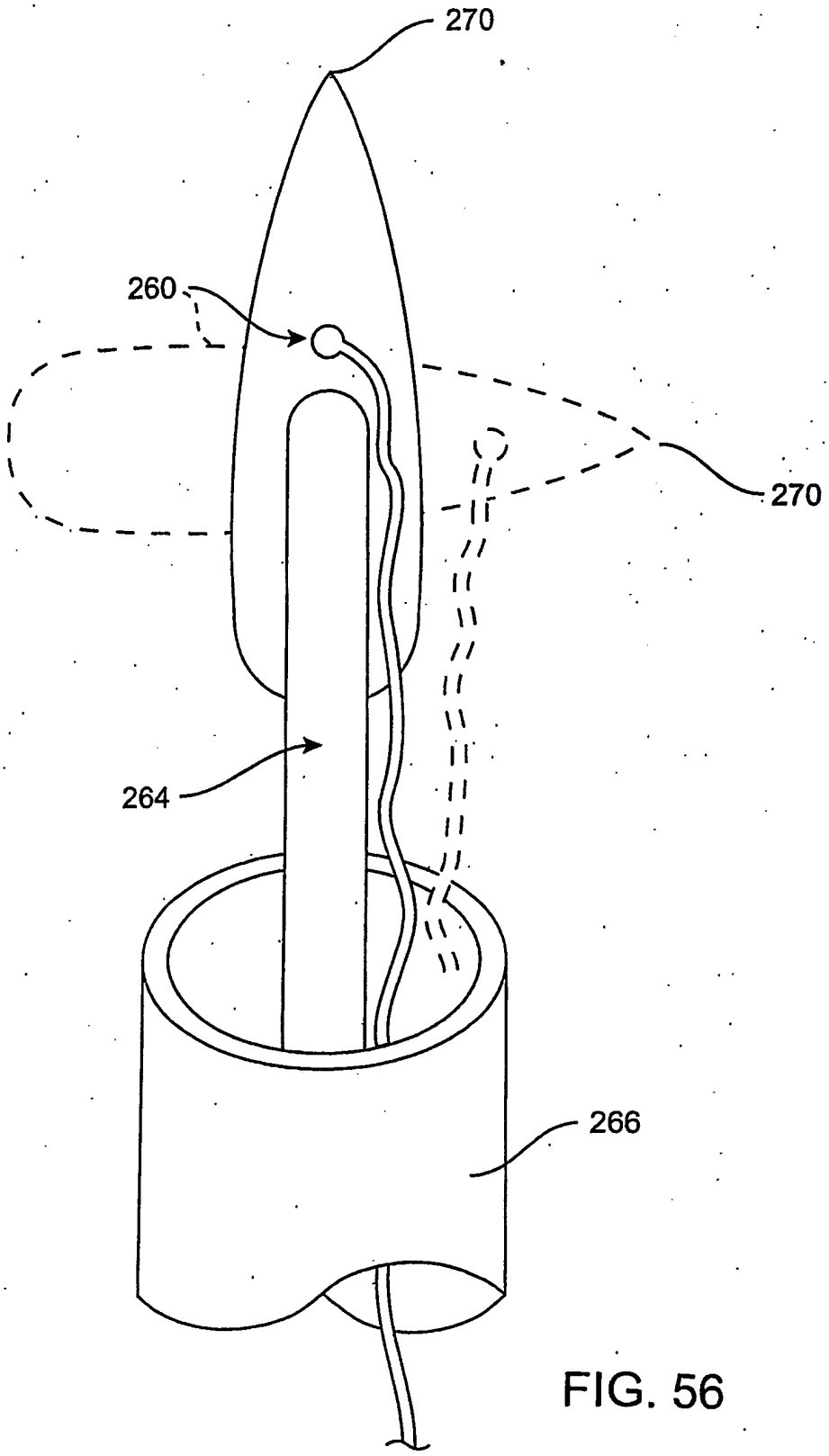


FIG. 56

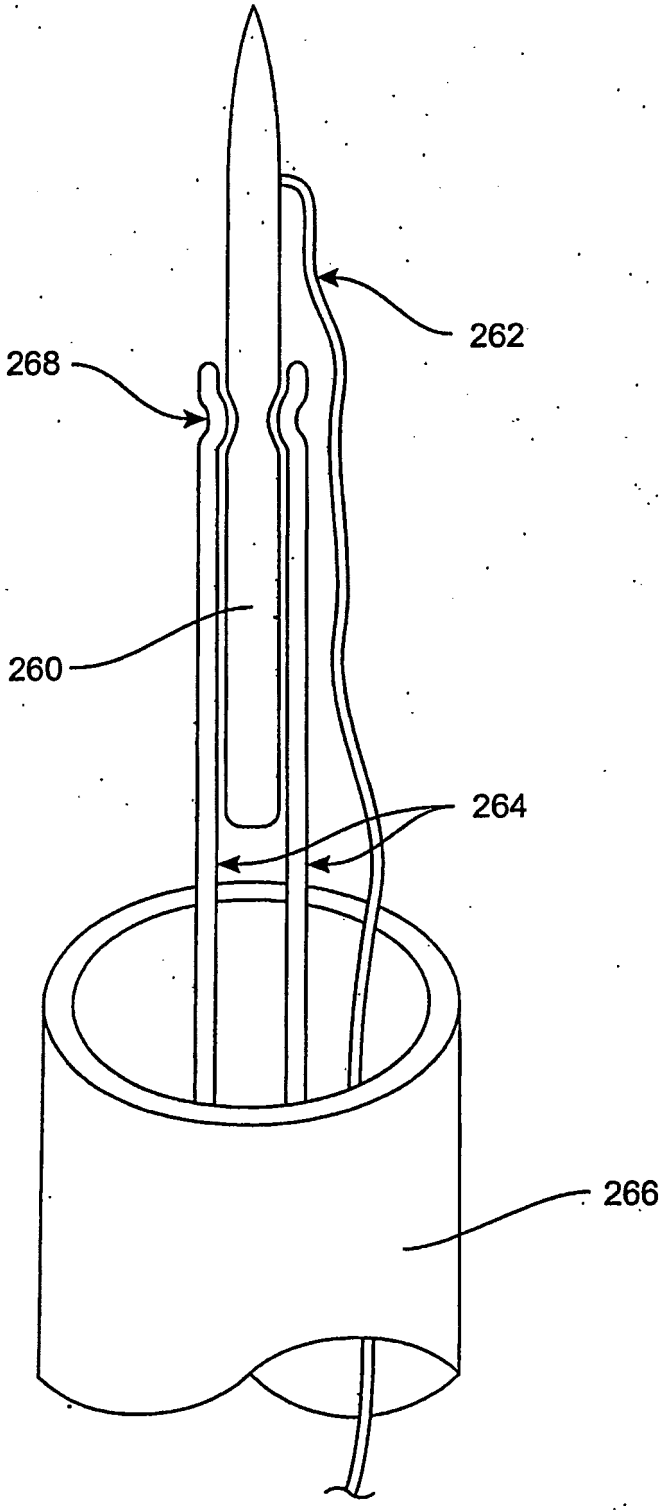


FIG. 57

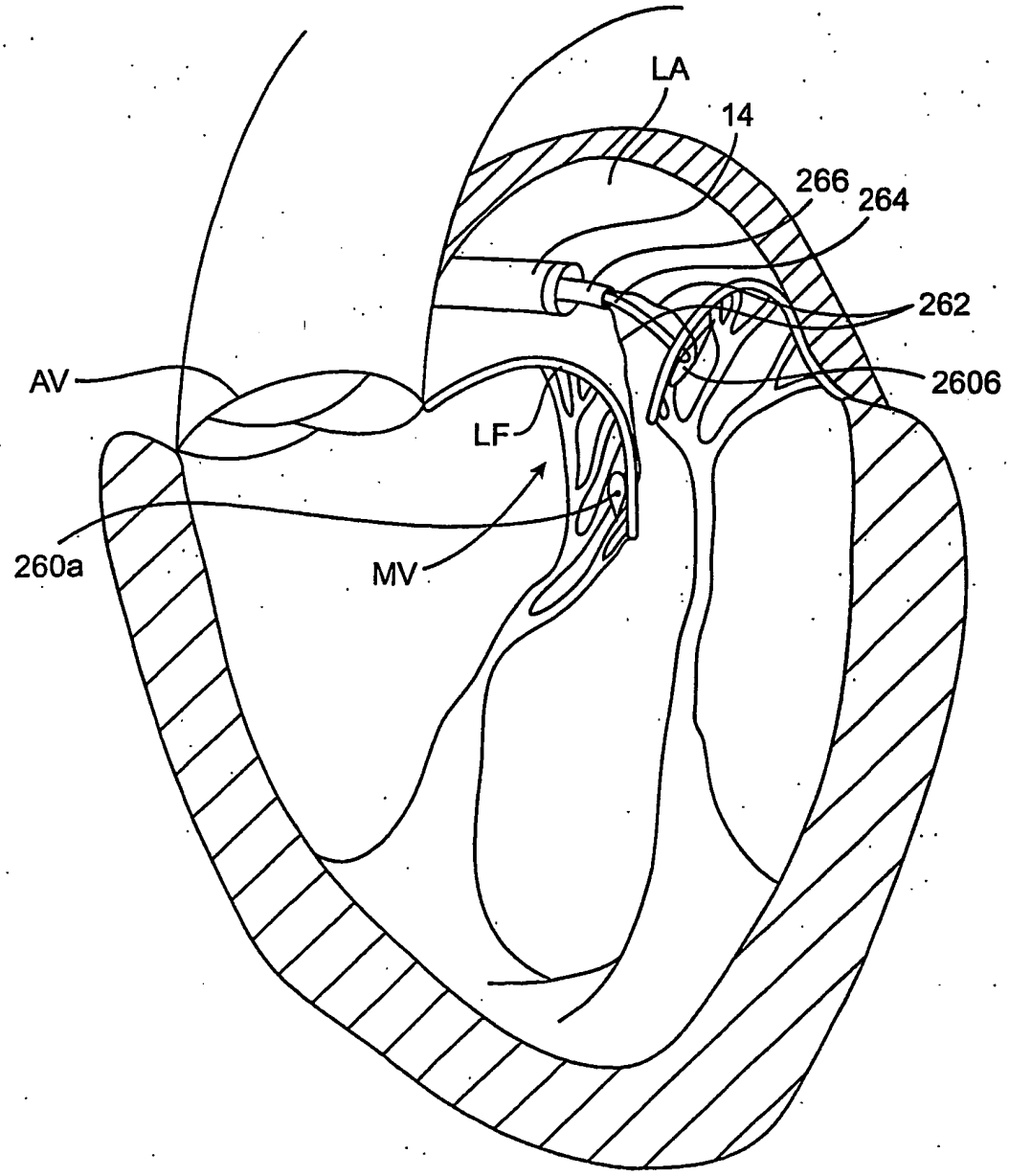


FIG. 58

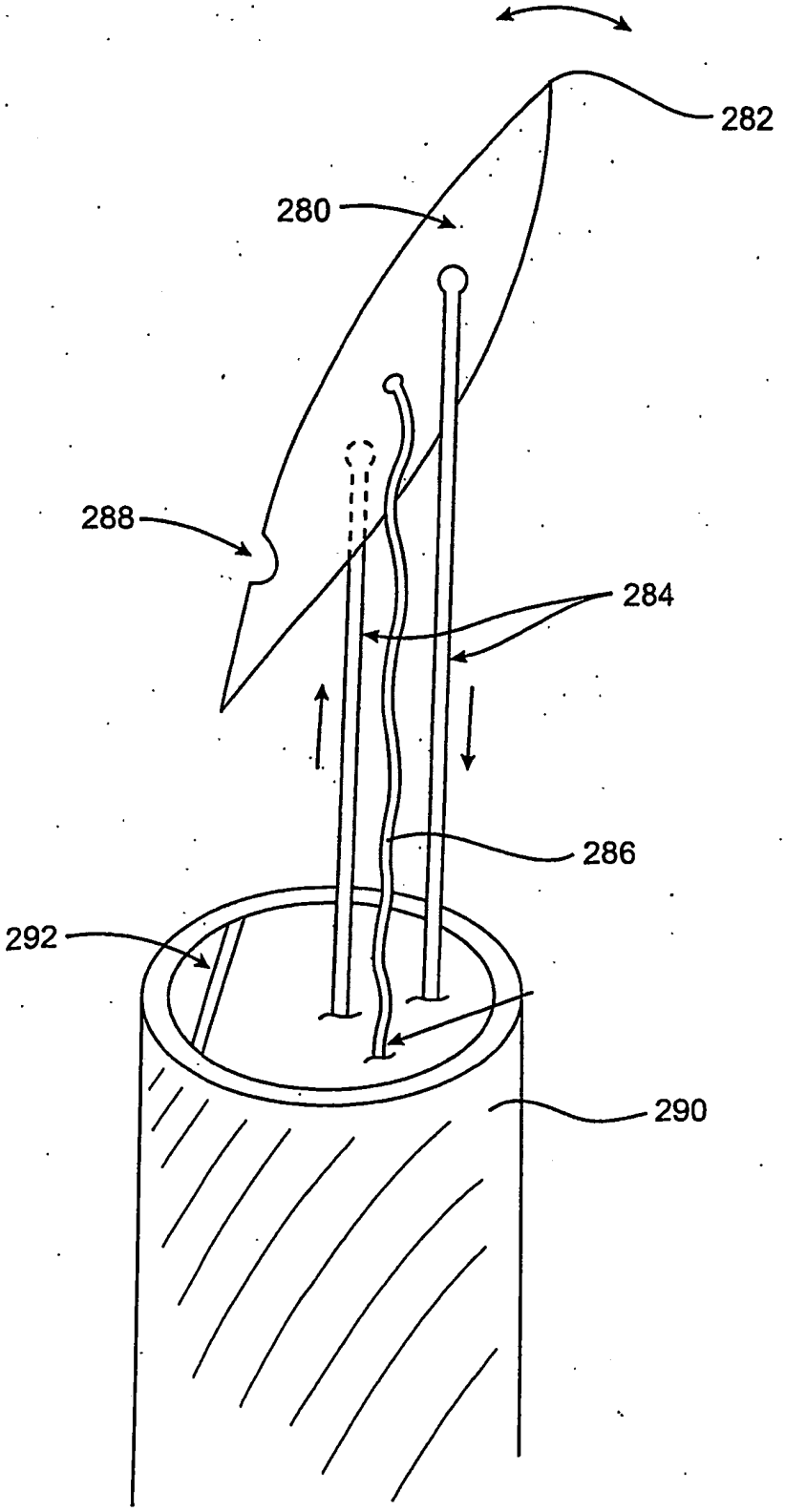


FIG. 59

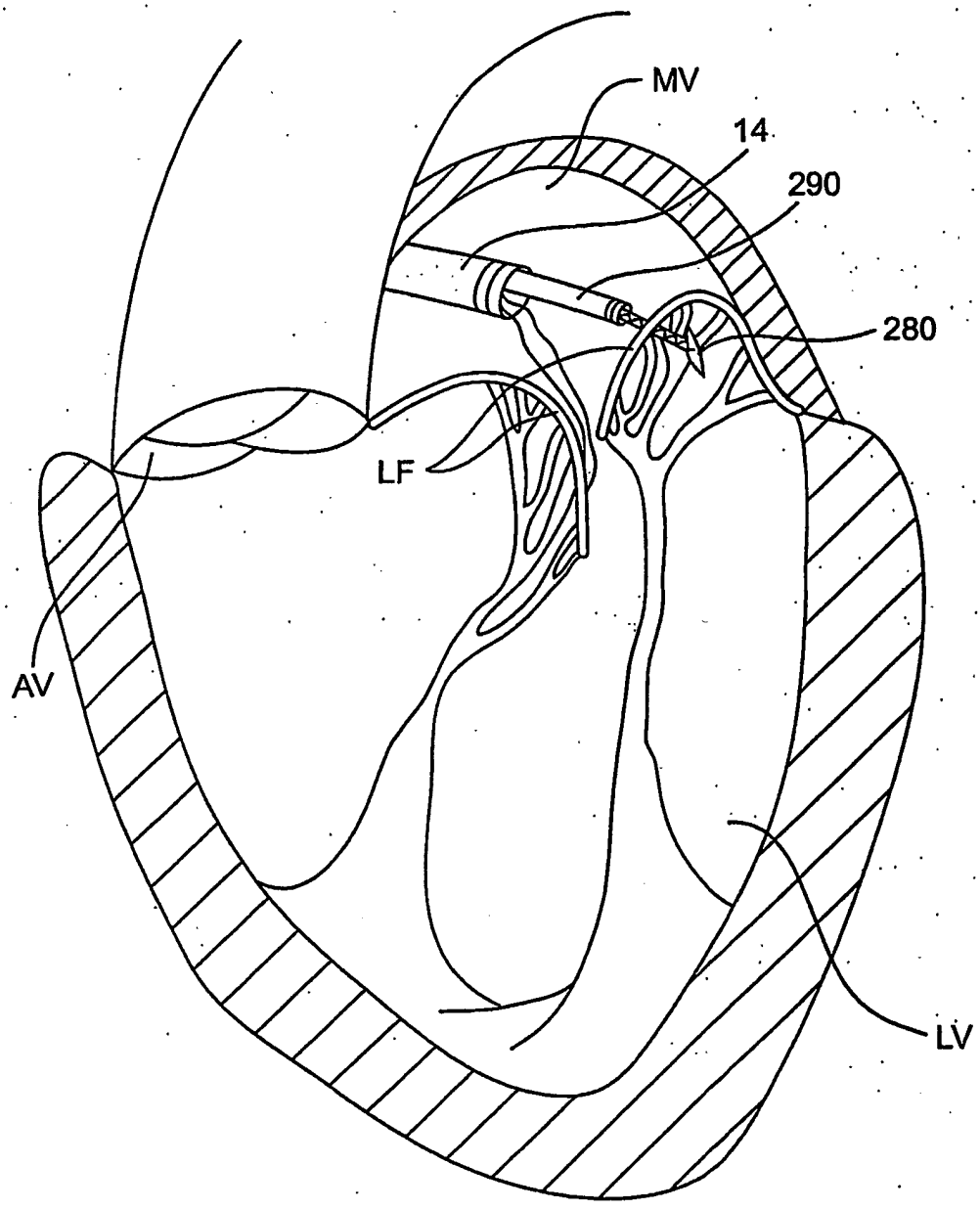


FIG. 60

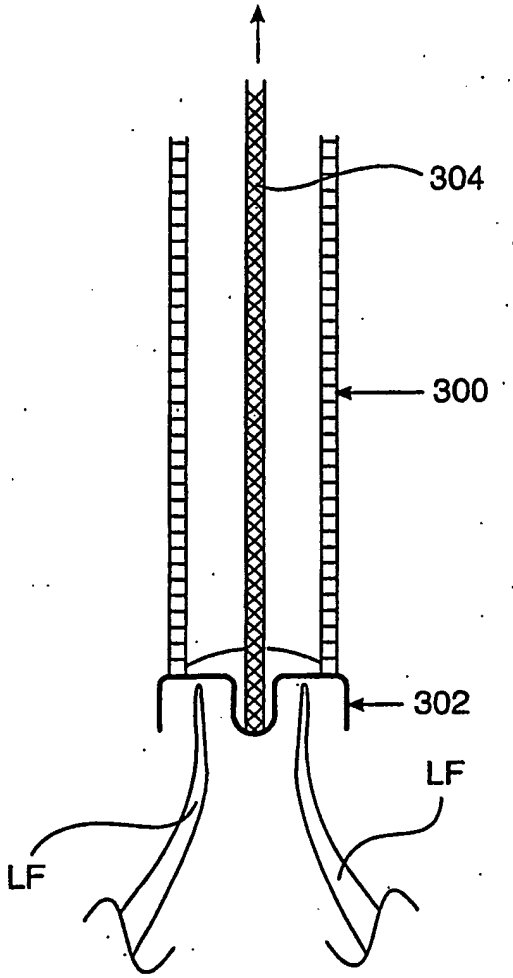


FIG. 61A

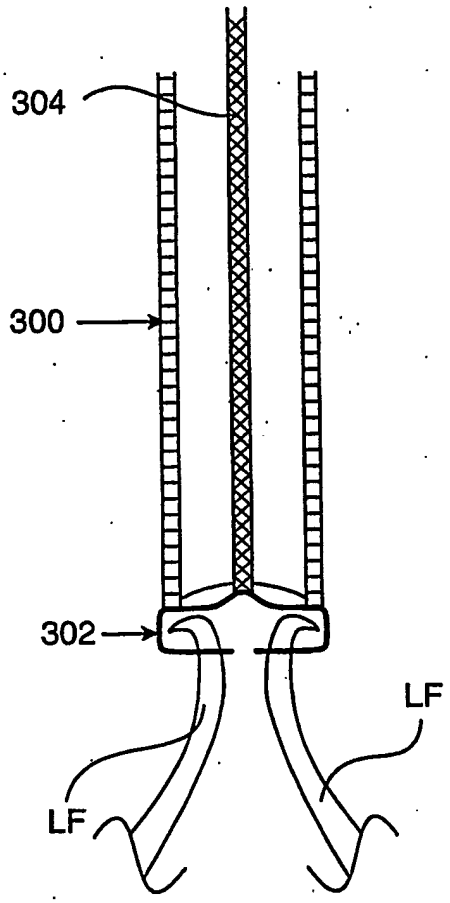


FIG. 61B

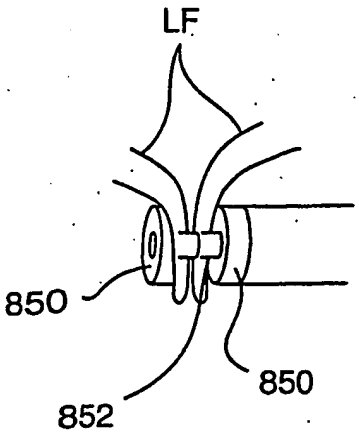


FIG. 62A

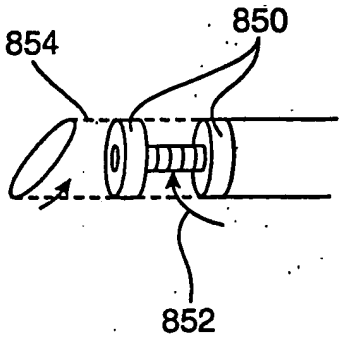


FIG. 62B

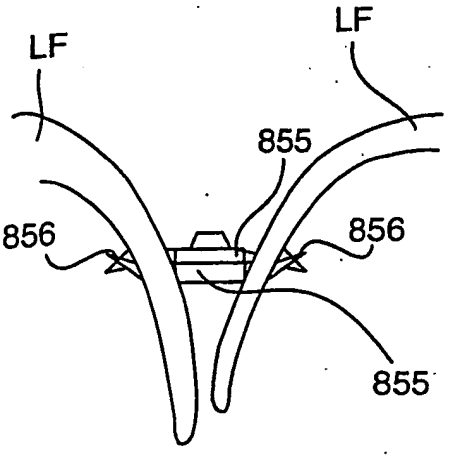


FIG. 62C

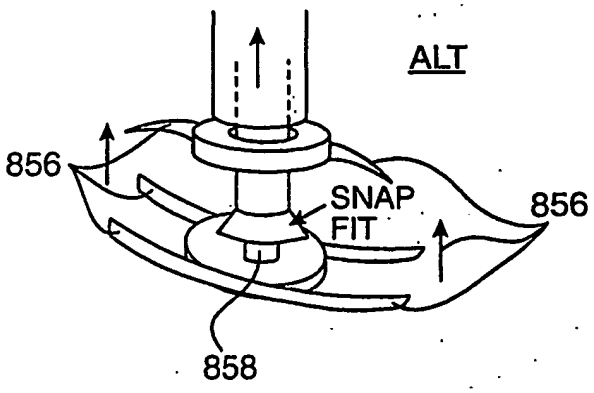


FIG. 62D

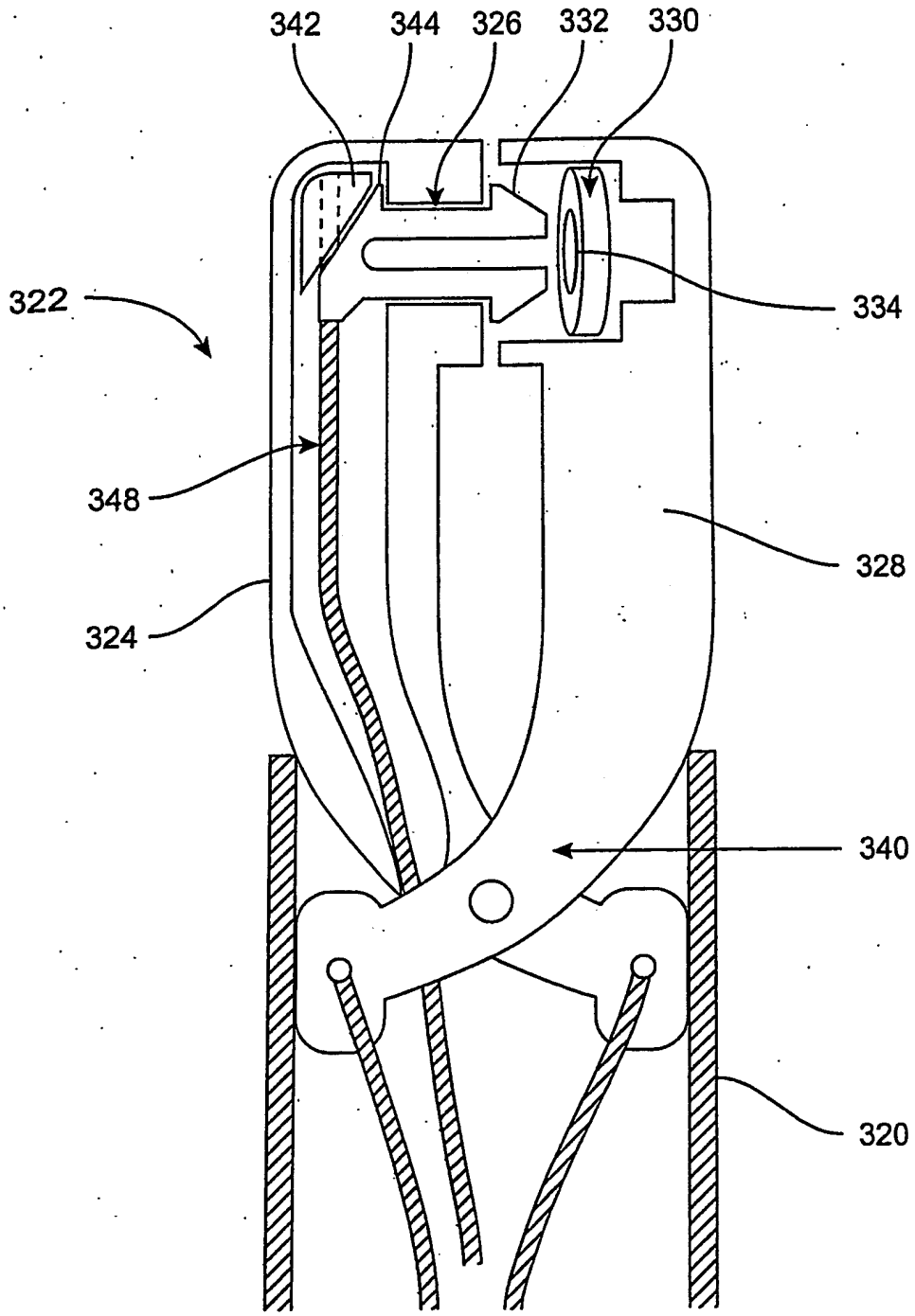


FIG. 63

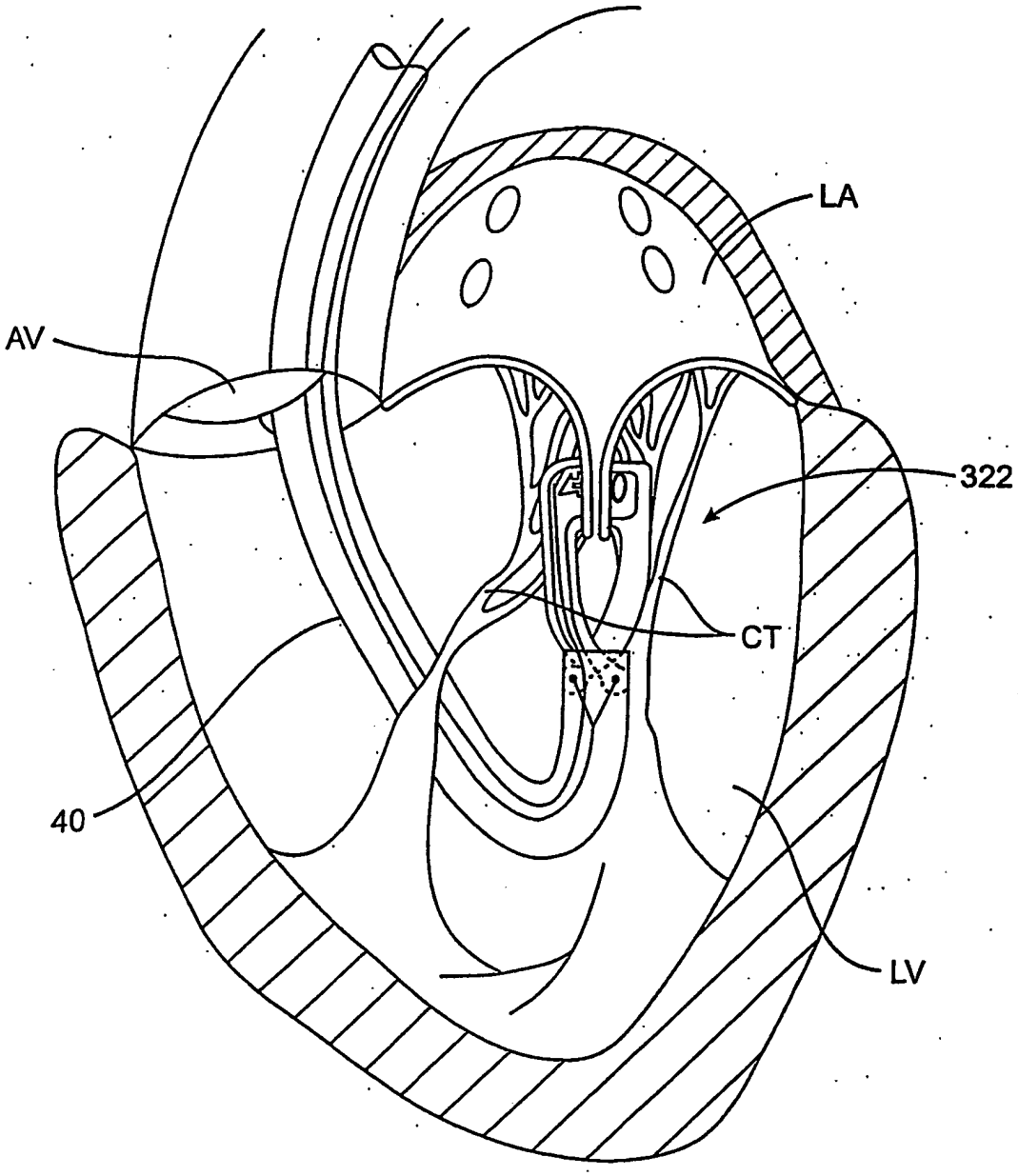


FIG. 64

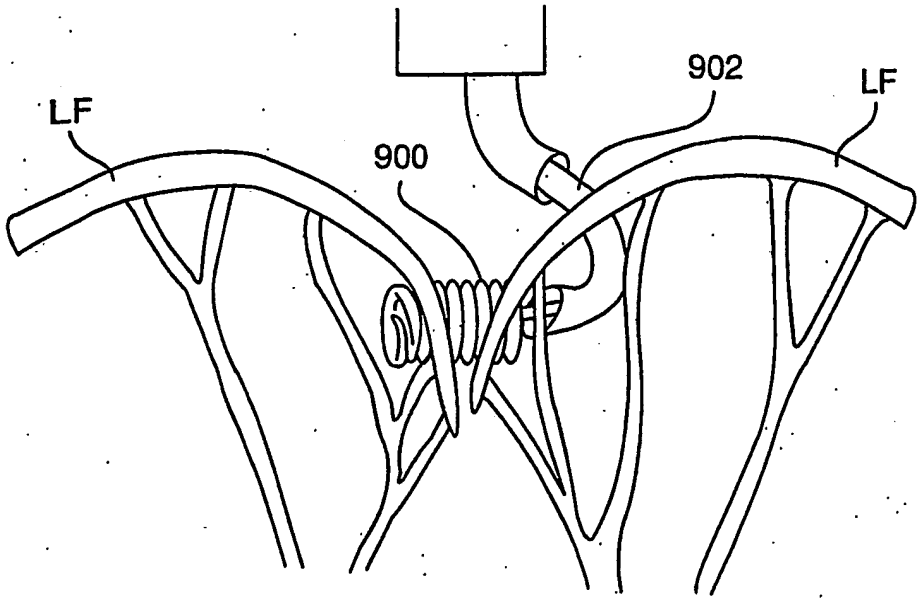


FIG. 65A

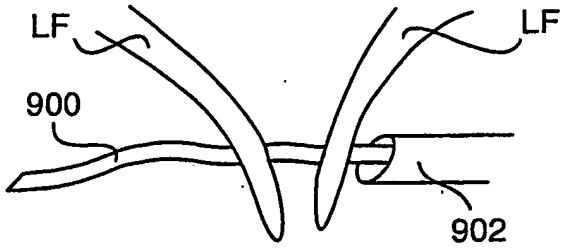


FIG. 65B

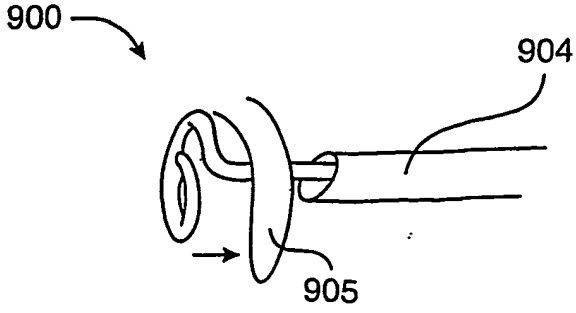


FIG. 65C

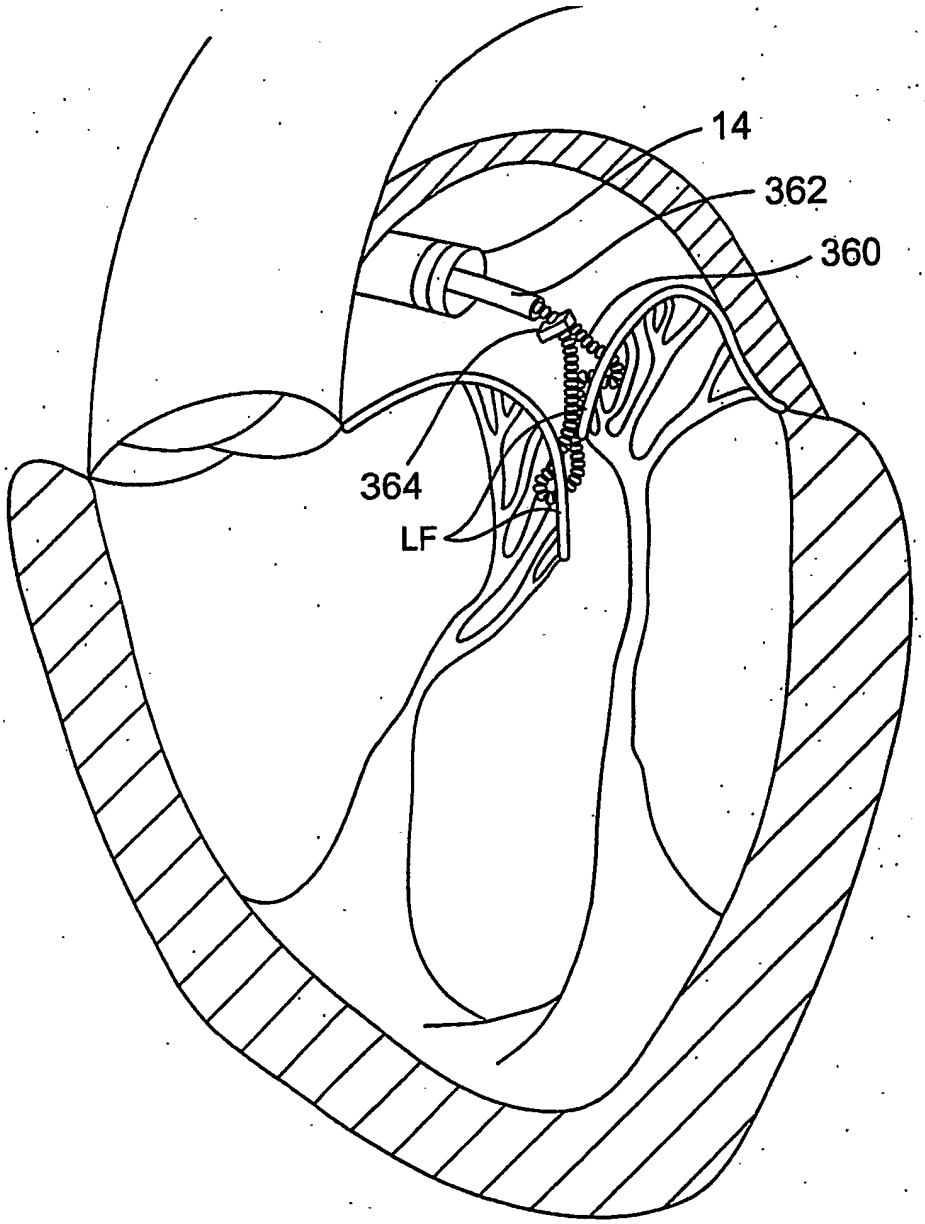


FIG. 66

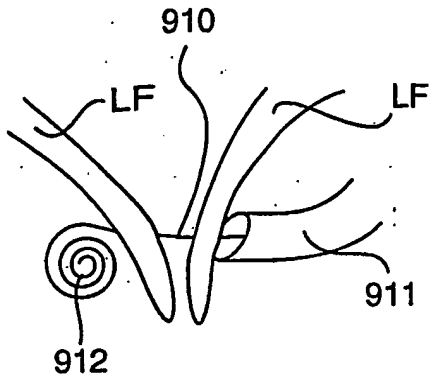


FIG. 66A

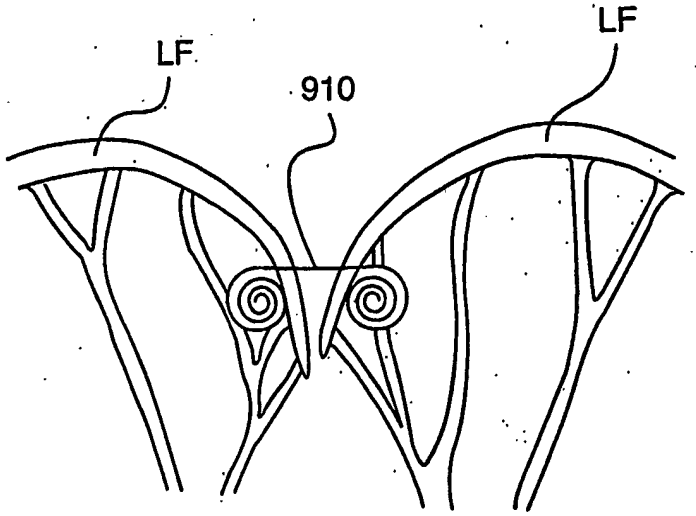


FIG. 66B

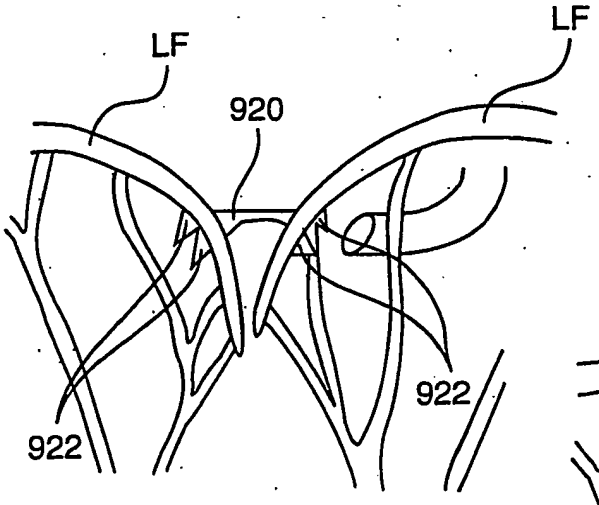


FIG. 67

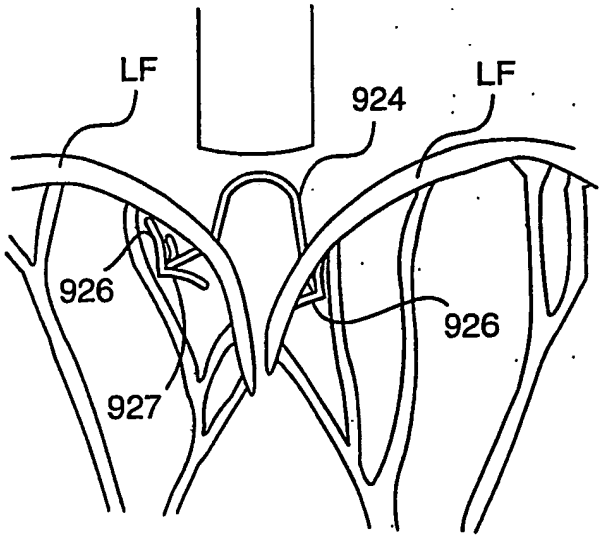


FIG. 68

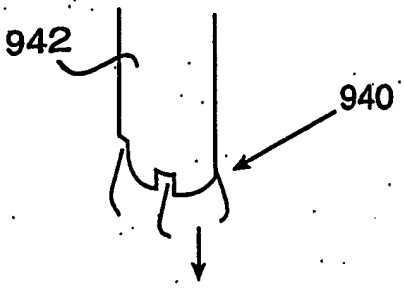


FIG. 69A

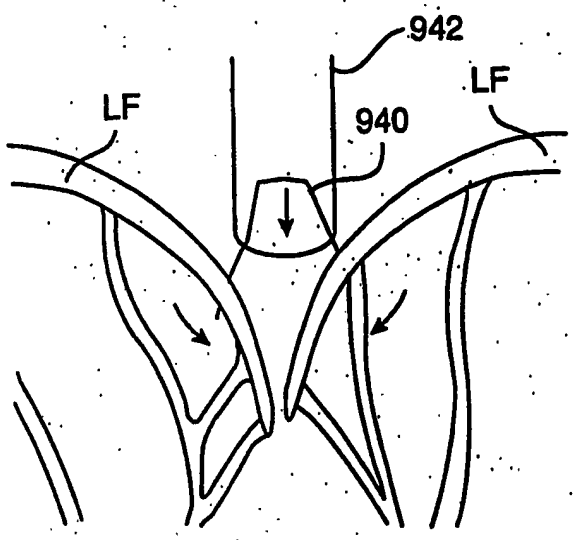


FIG. 69B

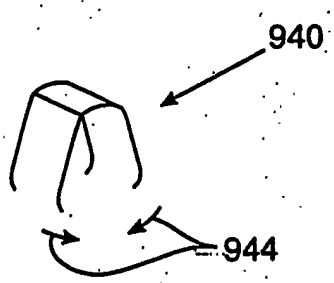


FIG. 69C

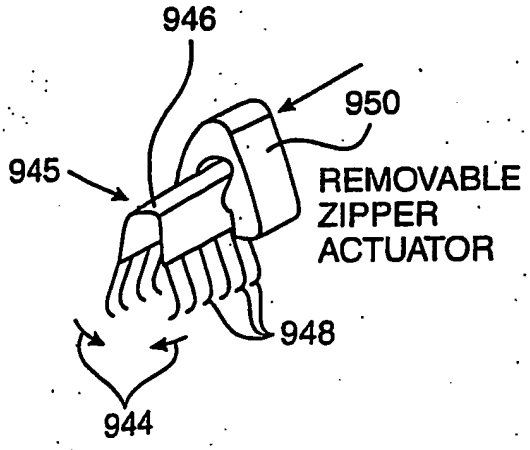


FIG. 70A

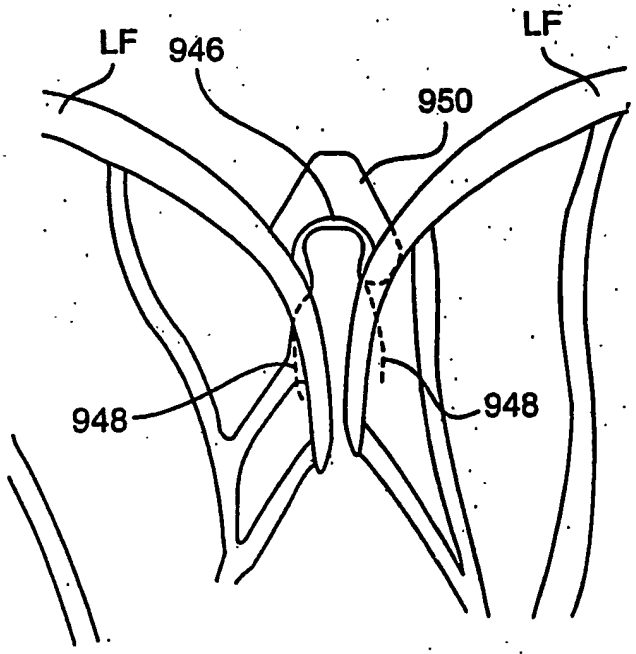


FIG. 70B

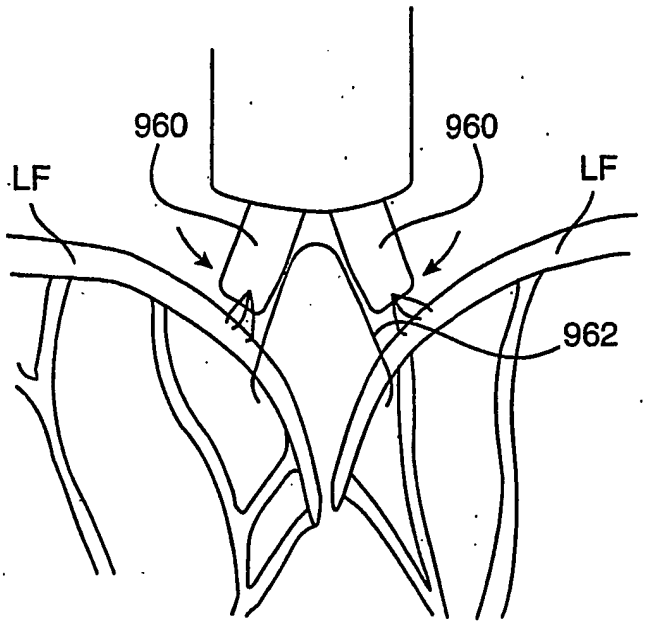


FIG. 71

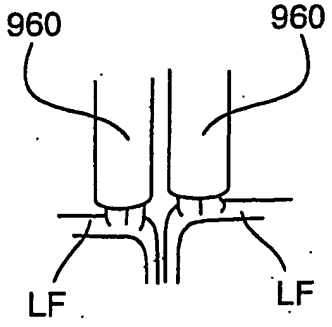


FIG. 72A

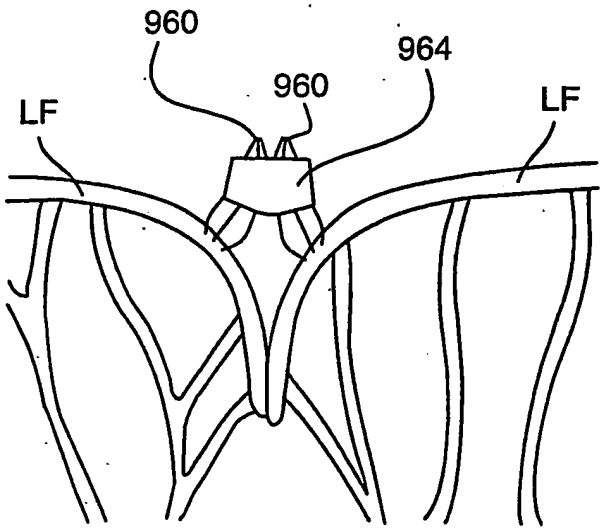


FIG. 72B

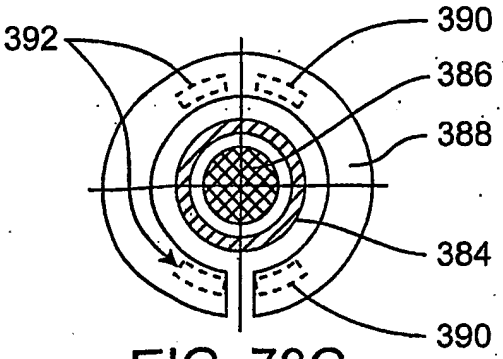


FIG. 73C

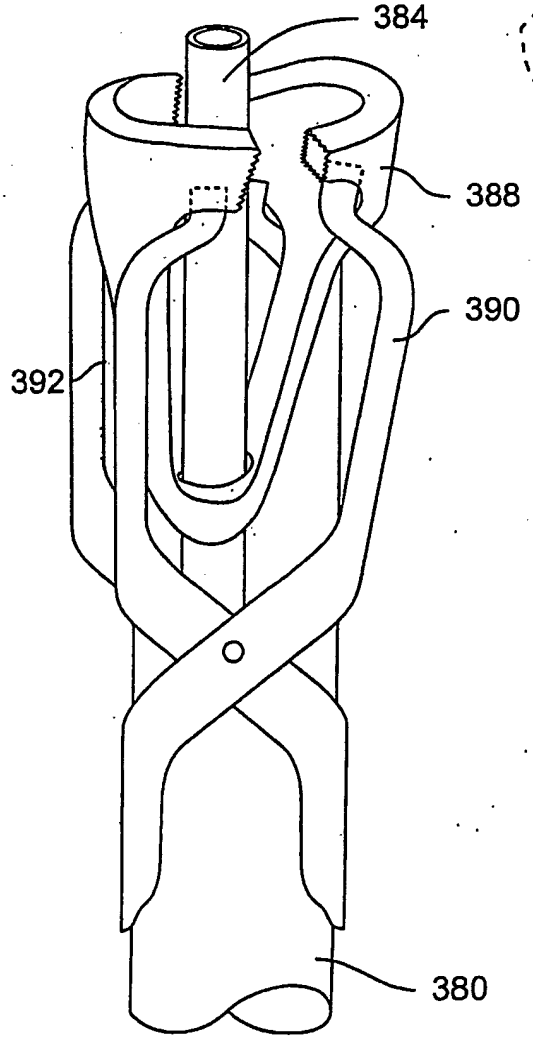


FIG. 73B

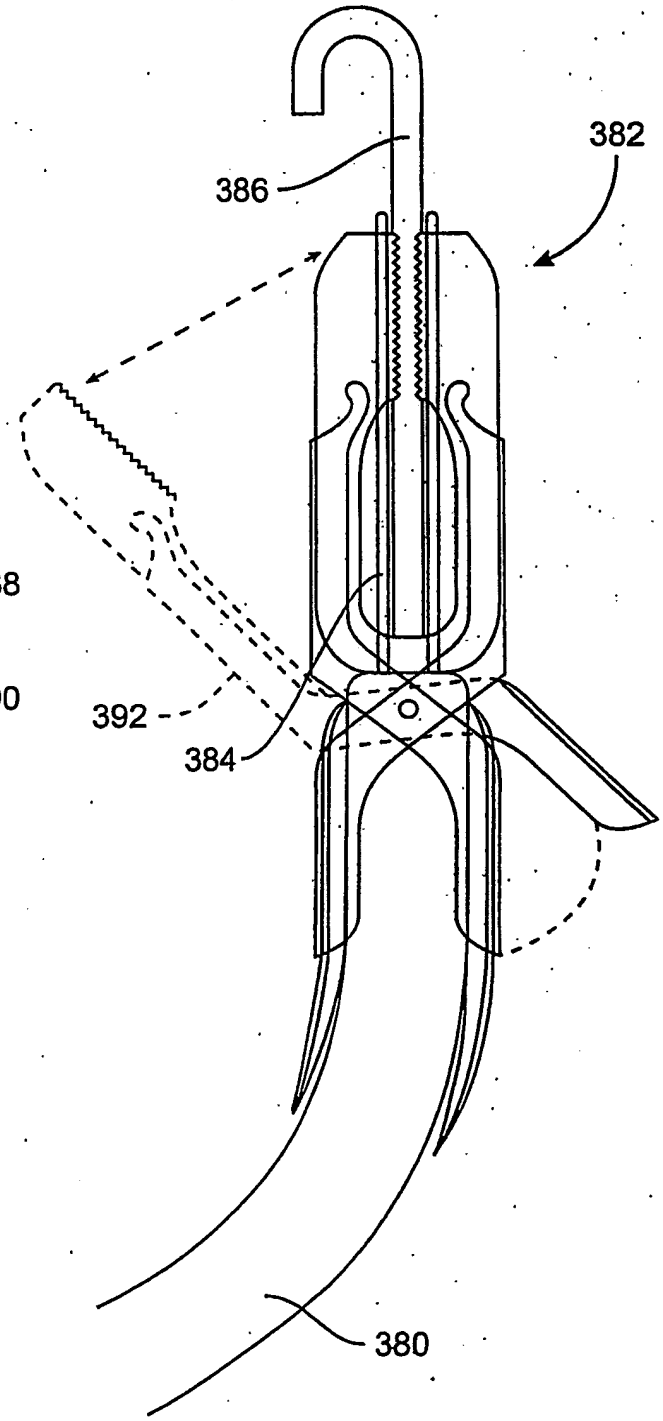


FIG. 73A

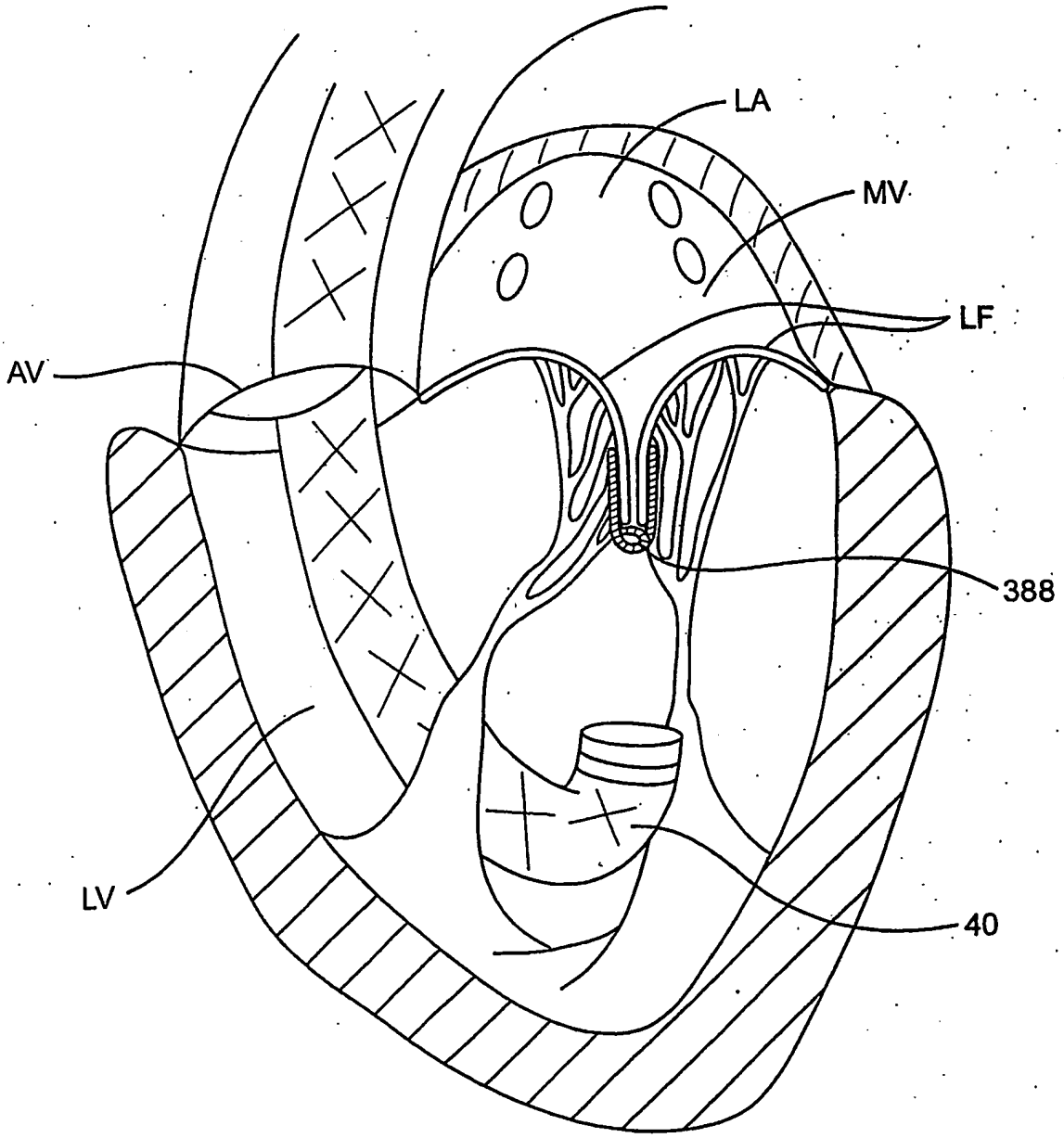


FIG. 74

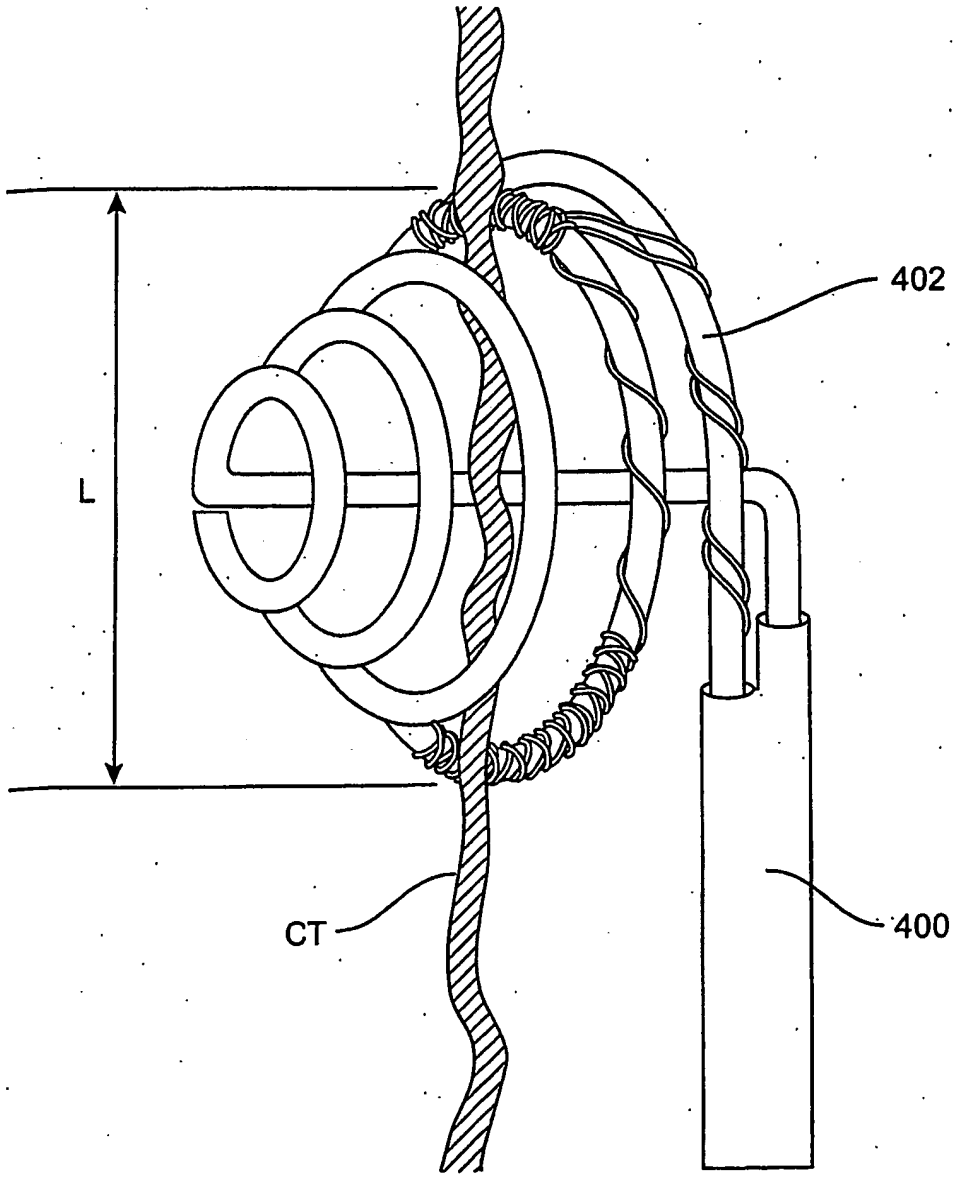


FIG. 75

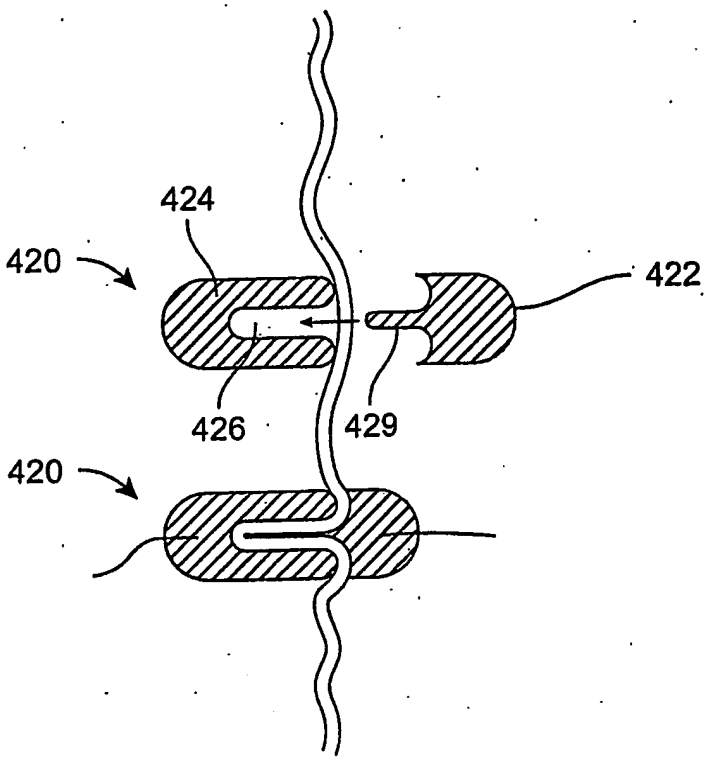


FIG. 76

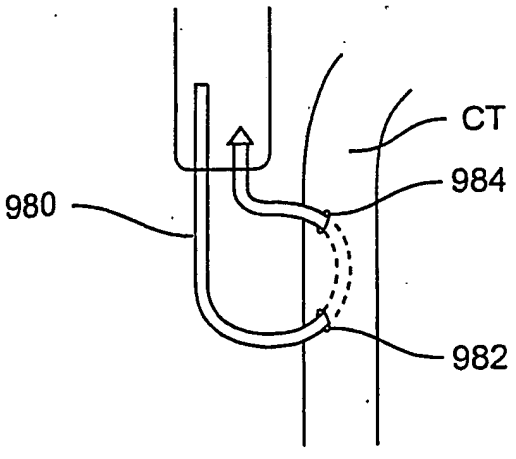


FIG. 77A

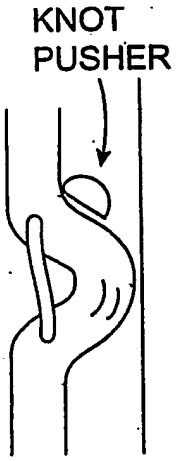


FIG. 77B

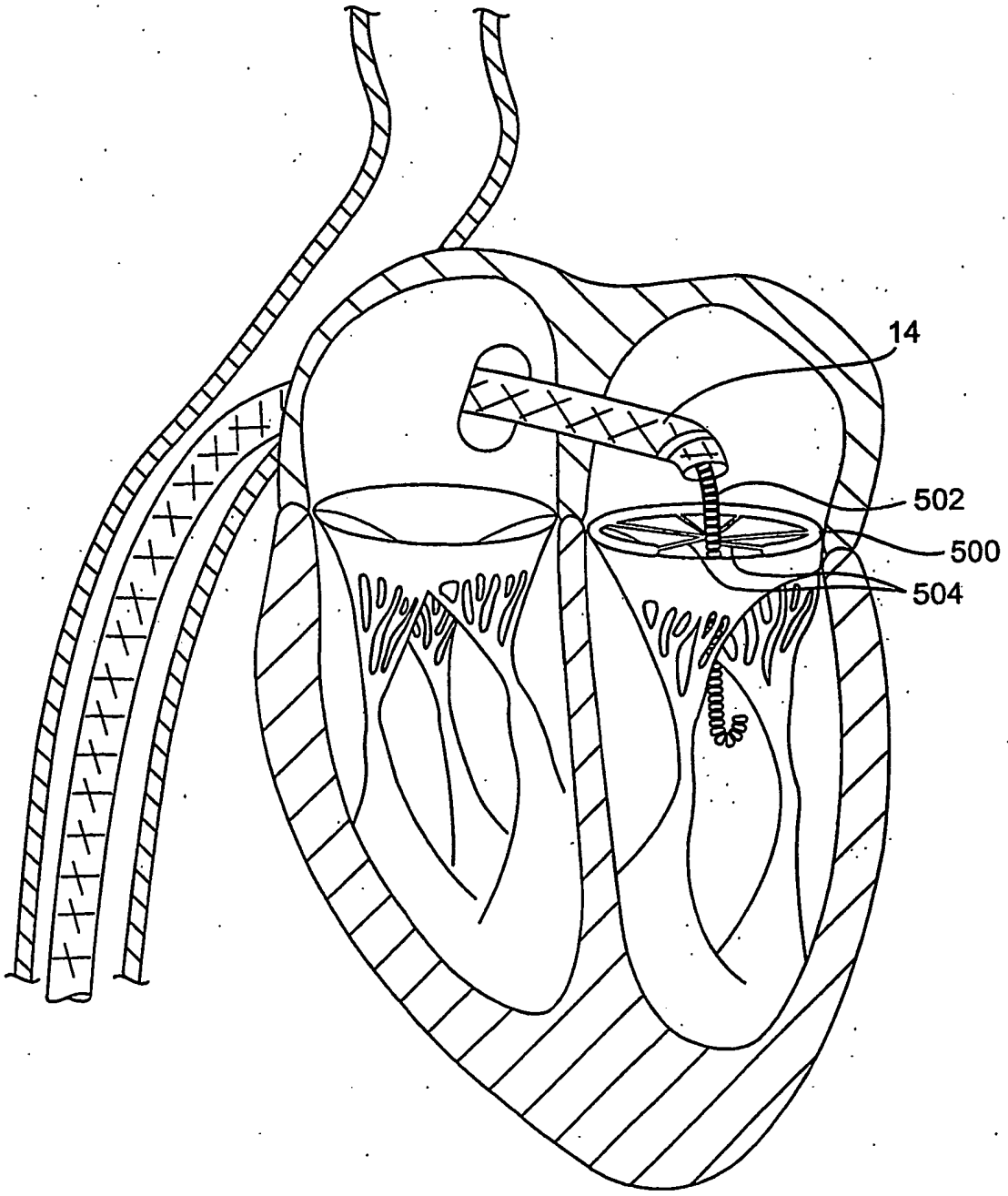


FIG. 78

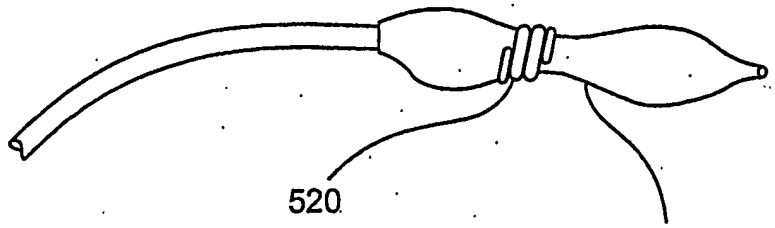


FIG. 79

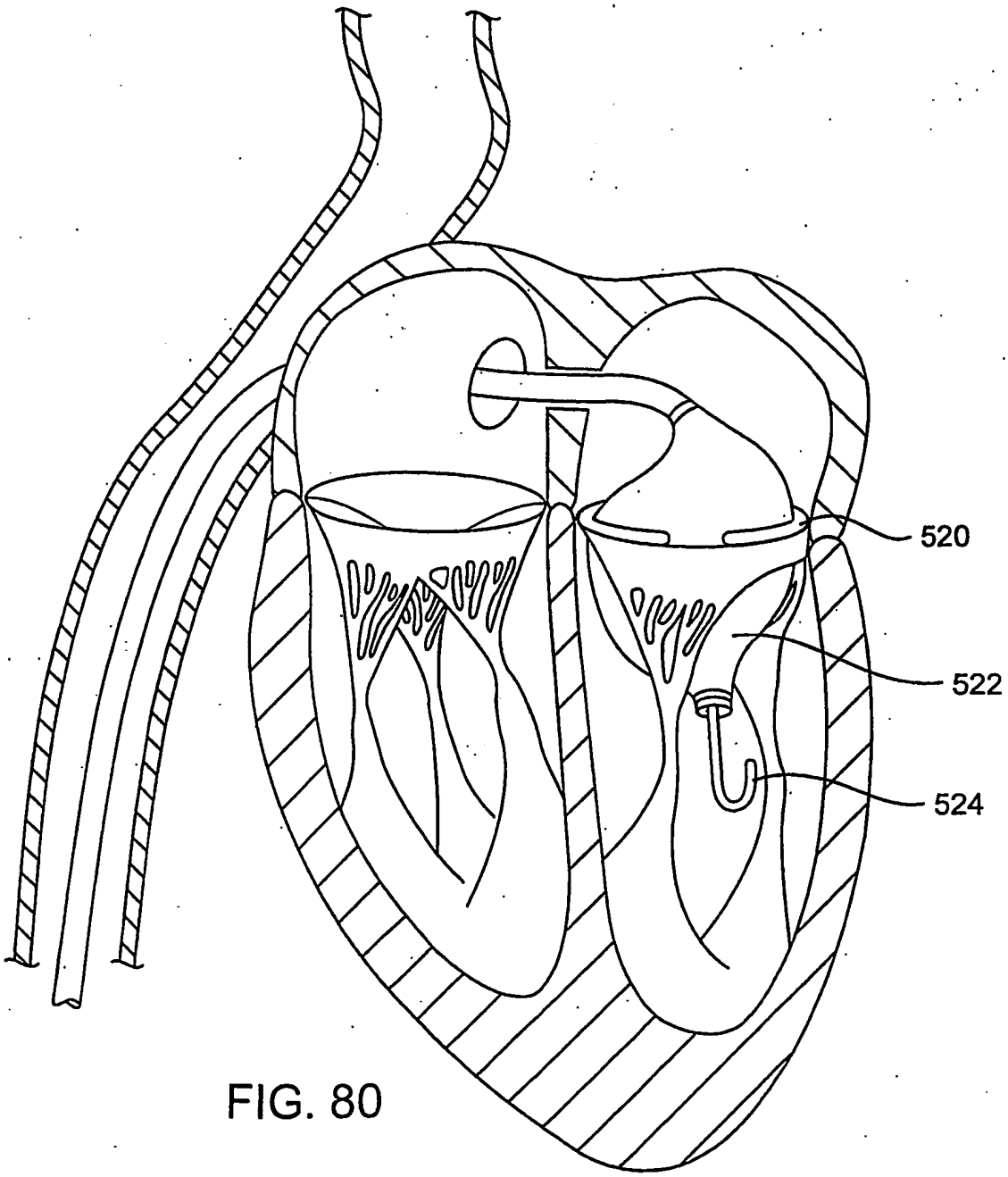


FIG. 80

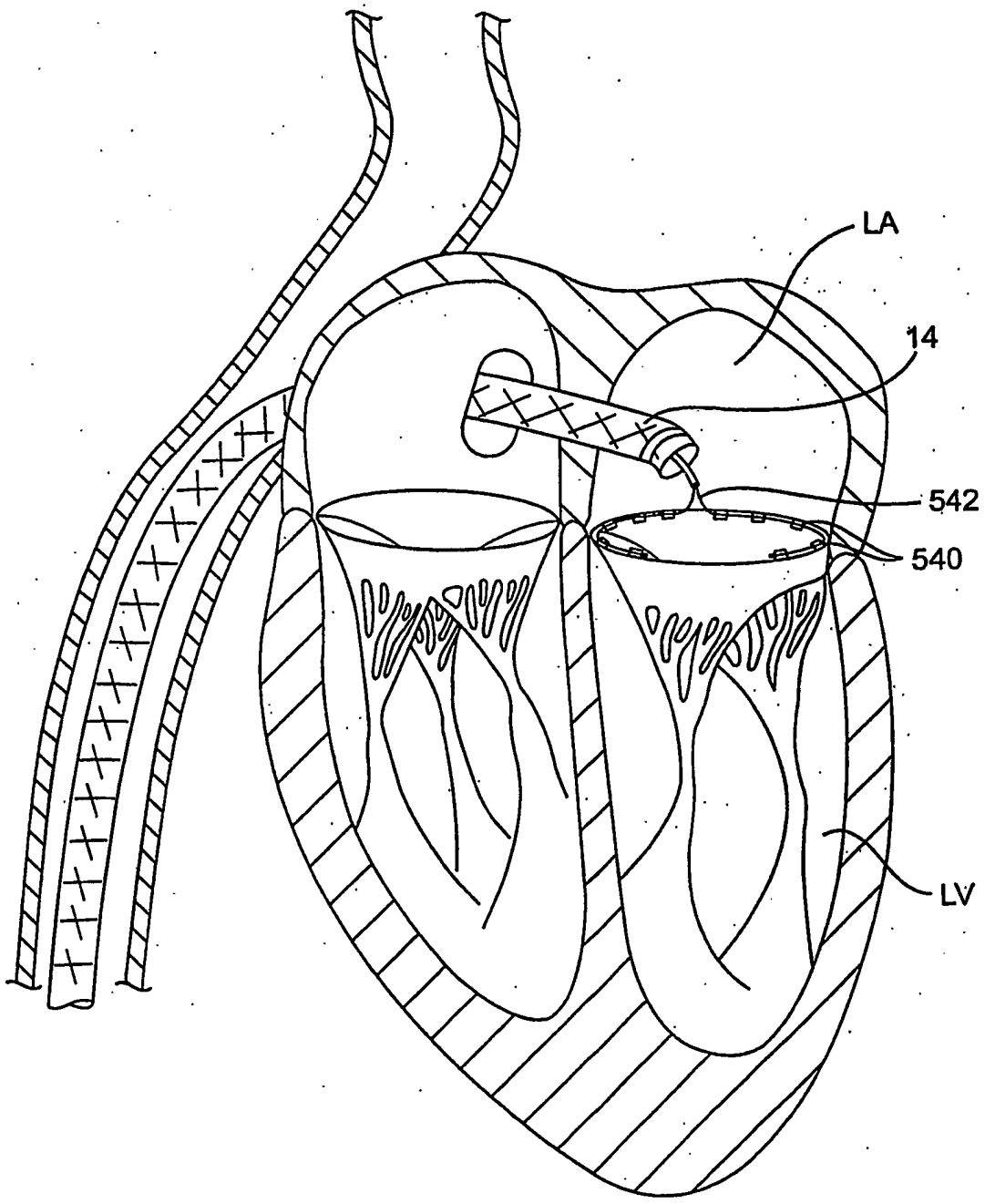


FIG. 81

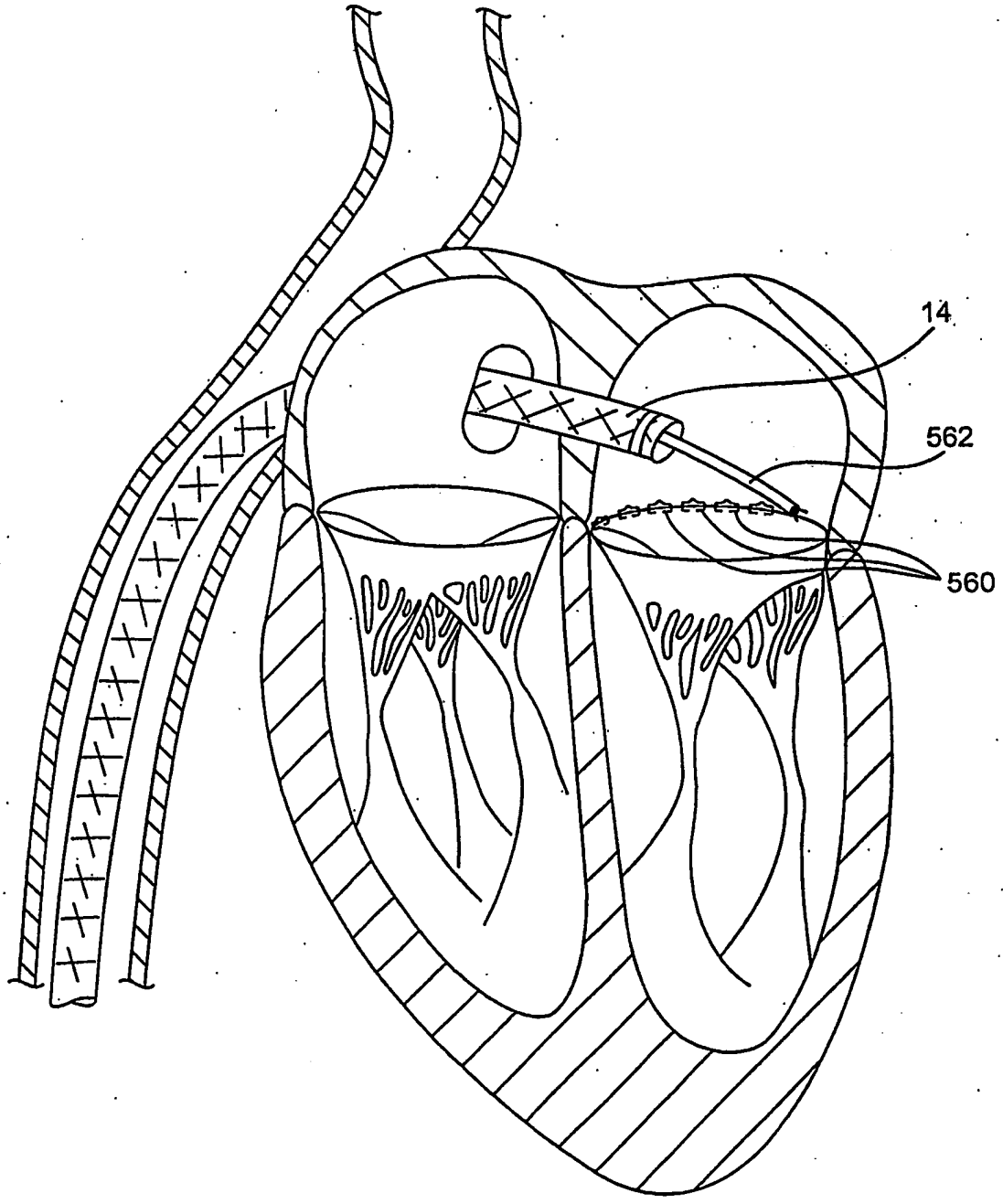
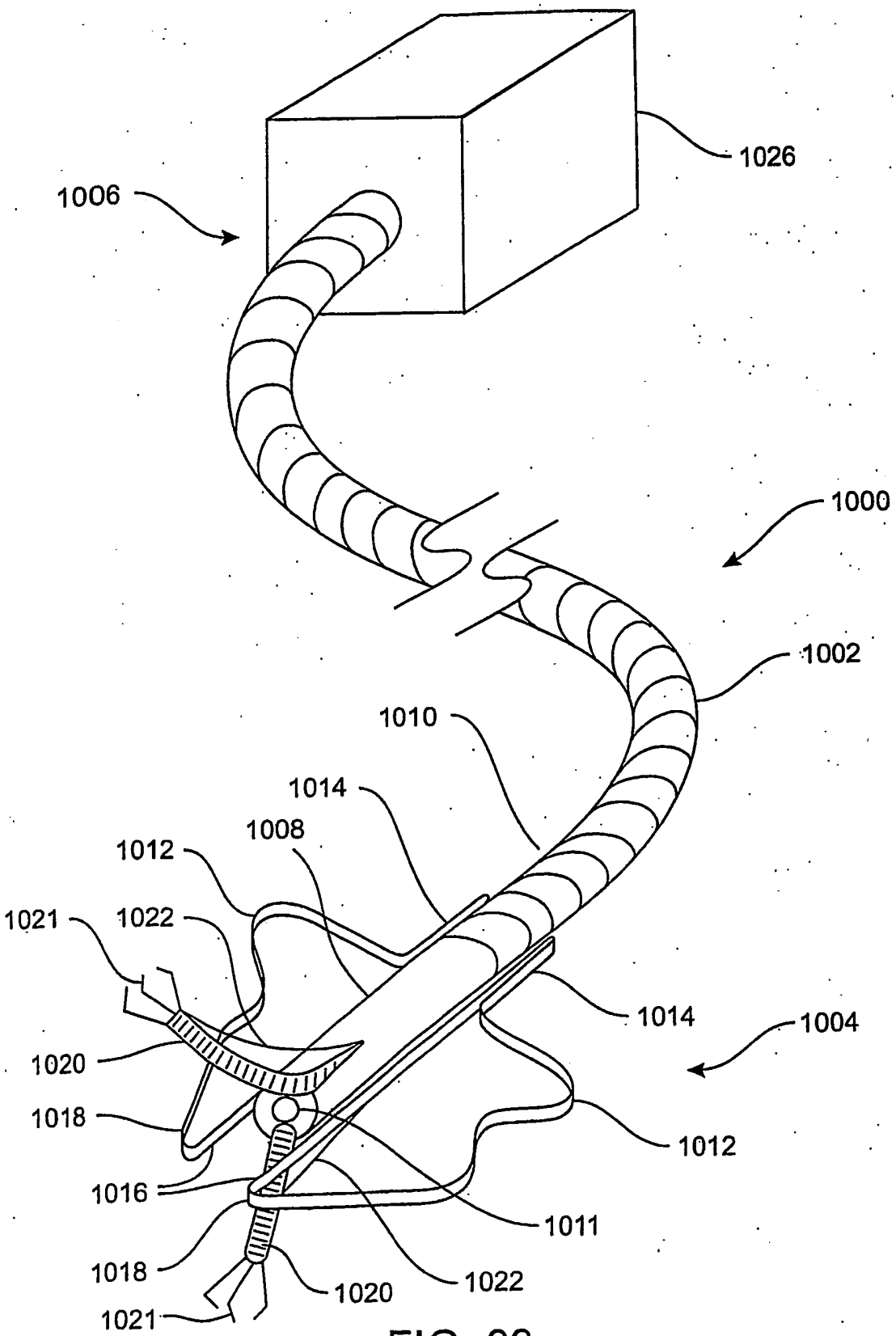


FIG. 82


1026
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1002
1010
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1012
1021
1022
1014
1004
1020
1018
1012
1016
1011
1018
1022
1020
1021

FIG. 83

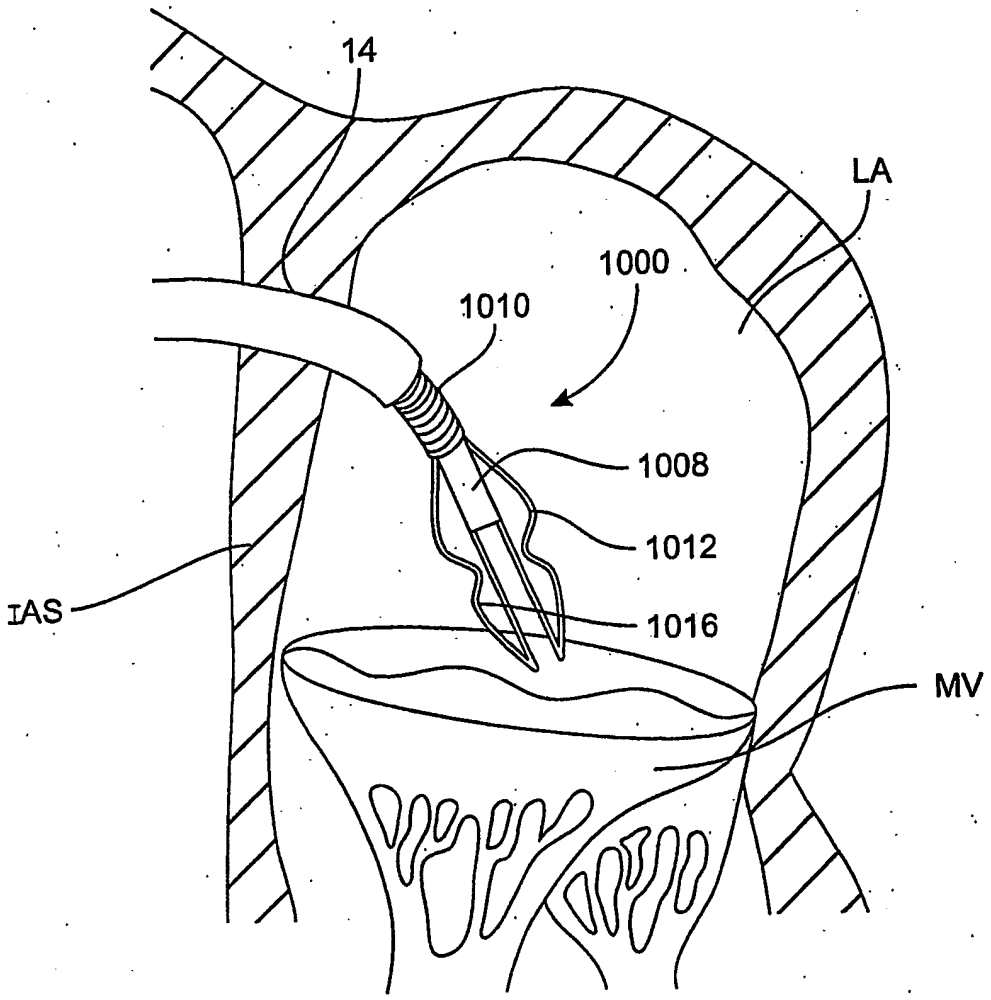


FIG. 84

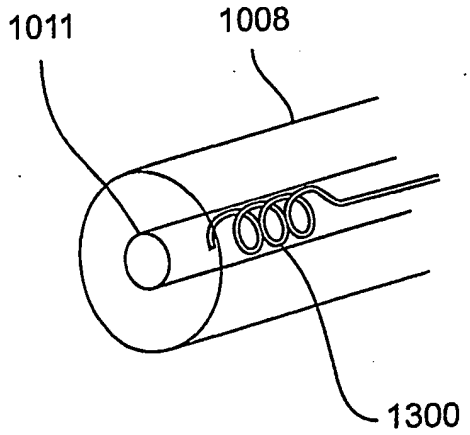


FIG. 84A

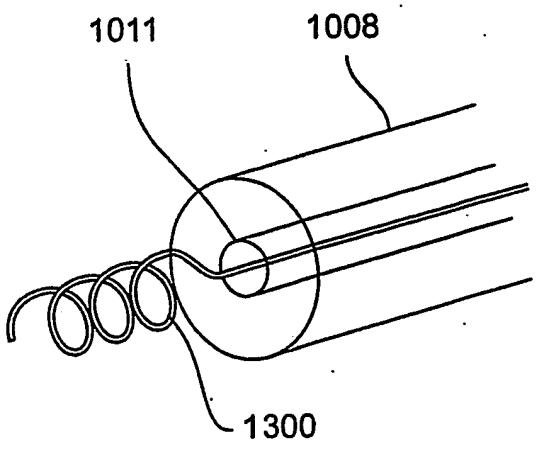
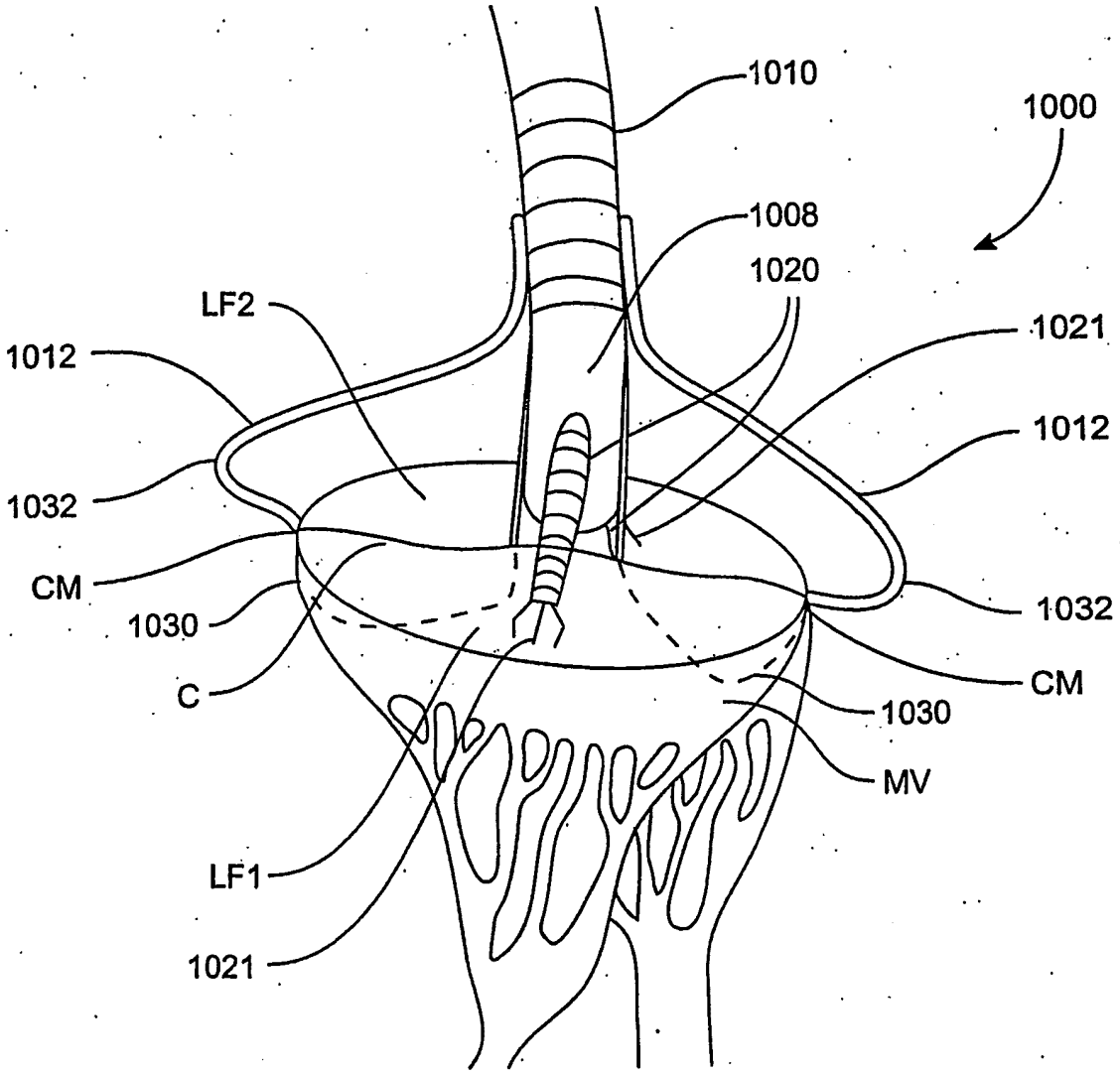


FIG. 84B


1010
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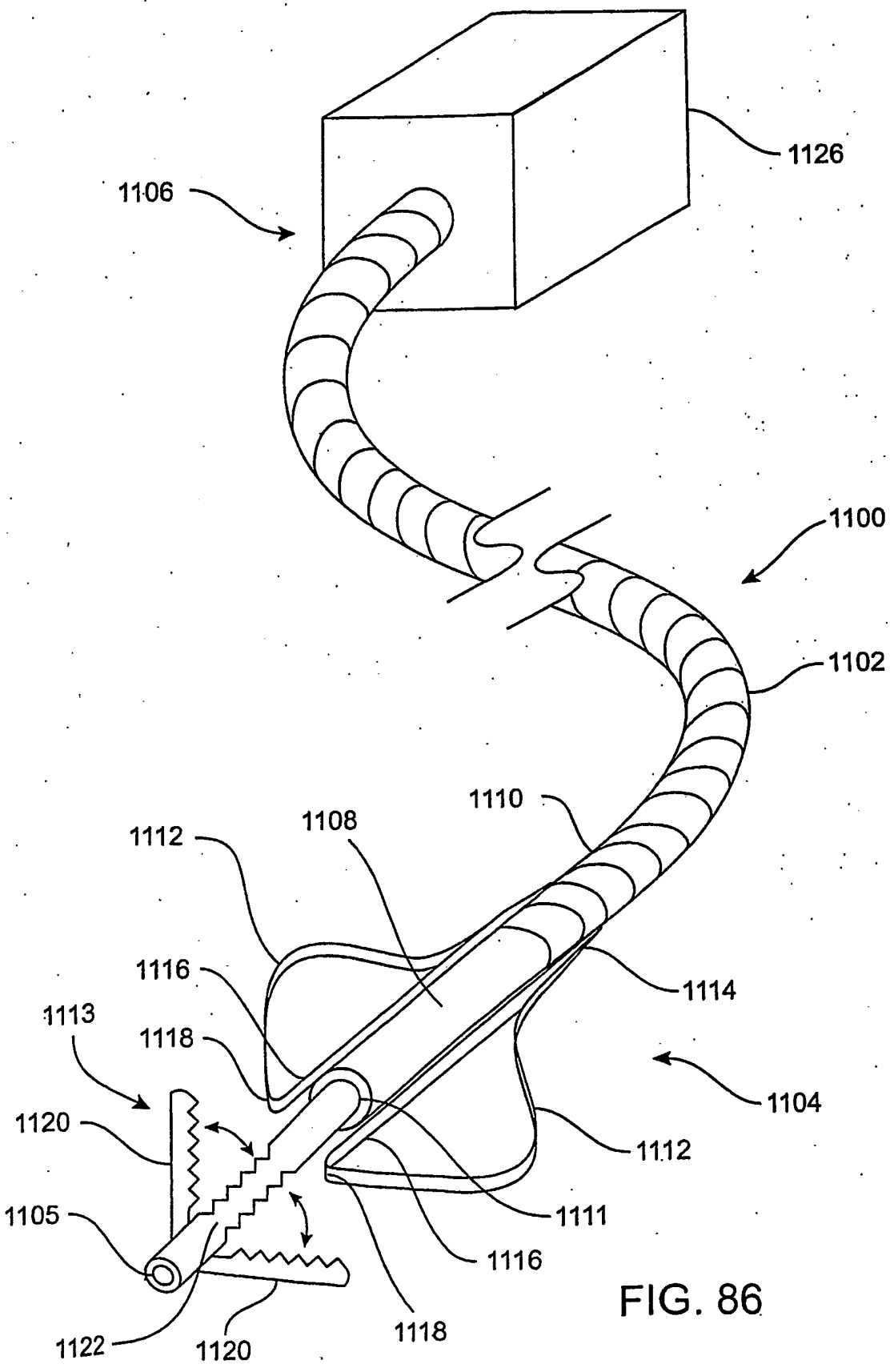
LF2
1021
1012
1012
1032
CM
1032
1030
C
CM
1030
MV
LF1
1021

FIG. 85


1126
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1120
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1111
1105
1116
1118
1122
1120

FIG. 86

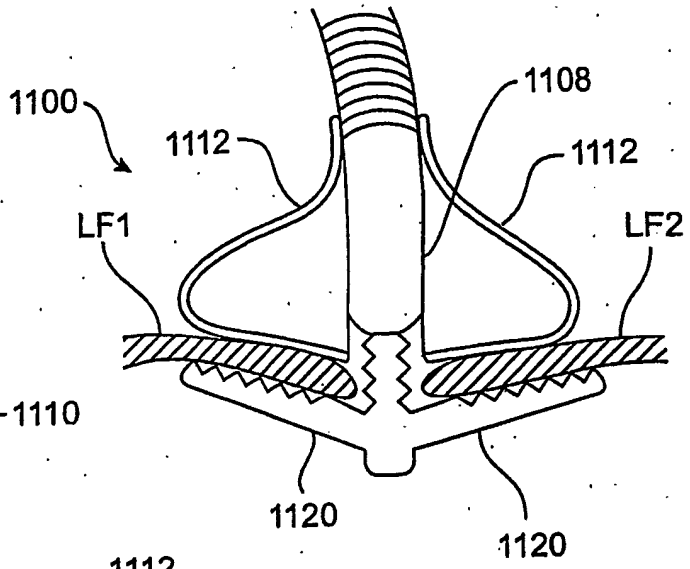

FIG. 87A

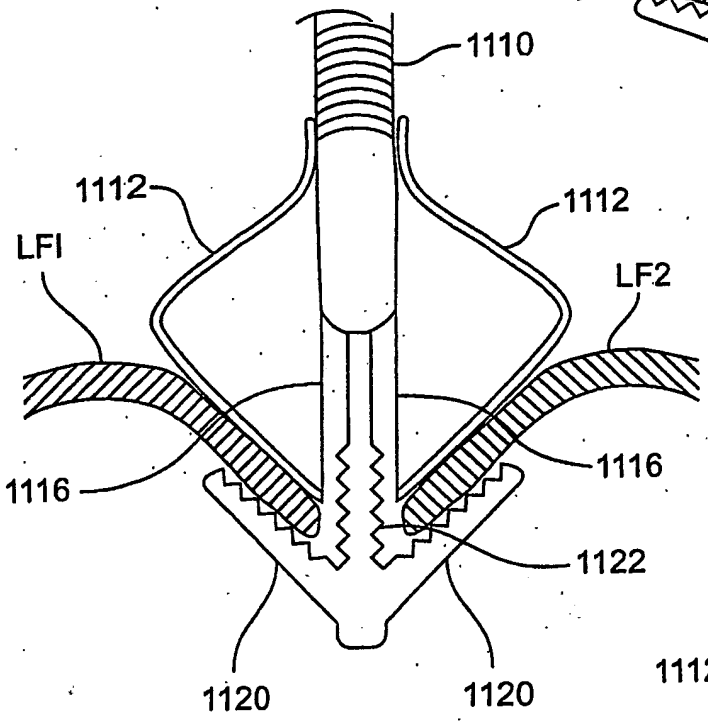

FIG. 87B

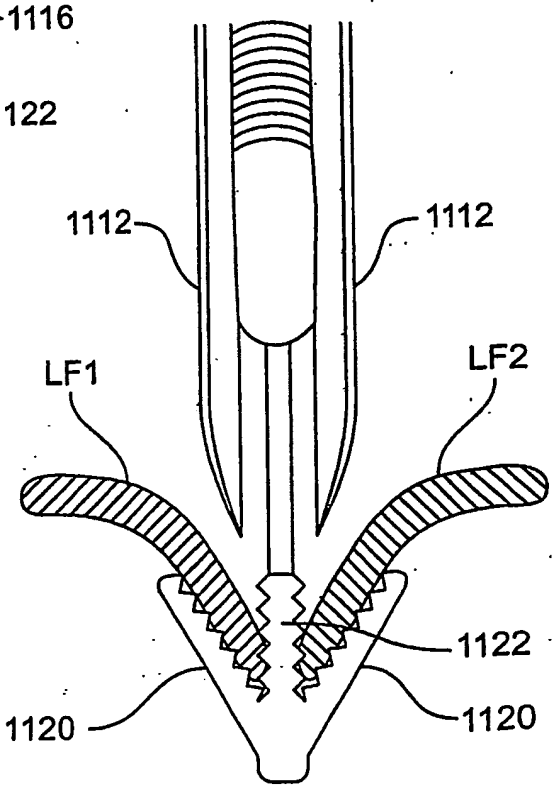

FIG. 87C

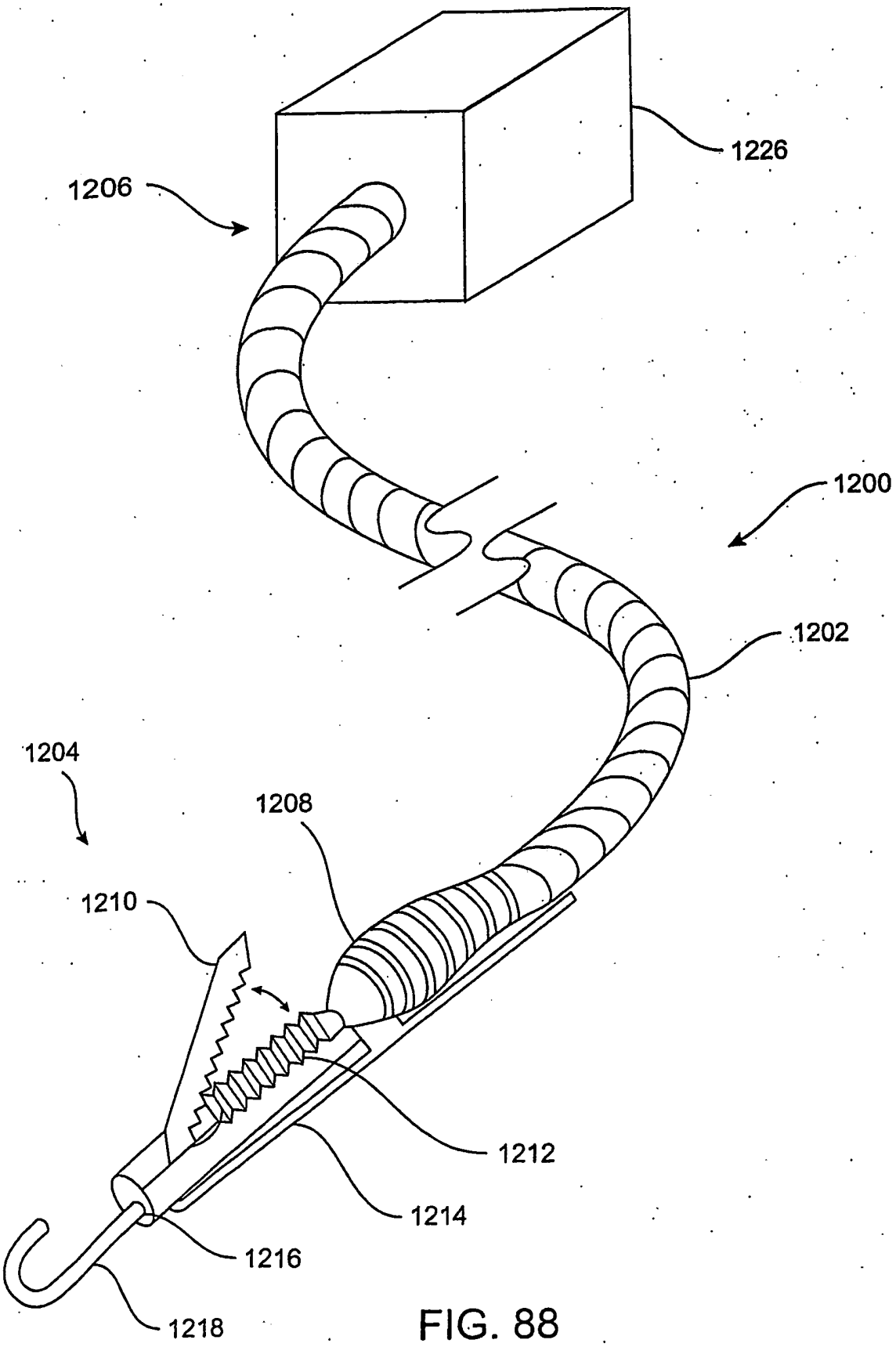

FIG. 88

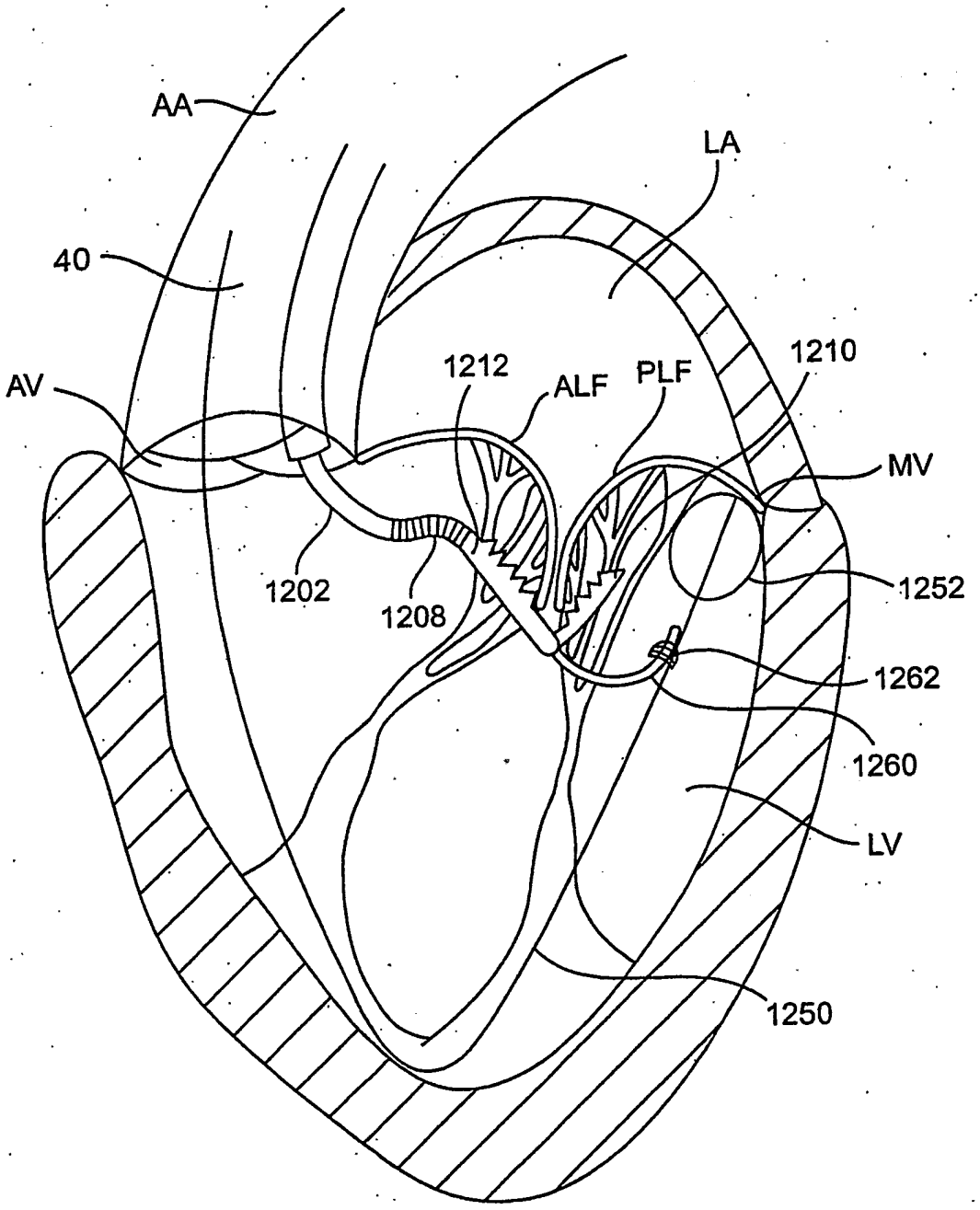
AA
LA
40
AV
1212
ALF
PLF
1210
MV
1202
1208
1252
1262
1260
LV
1250

FIG. 89

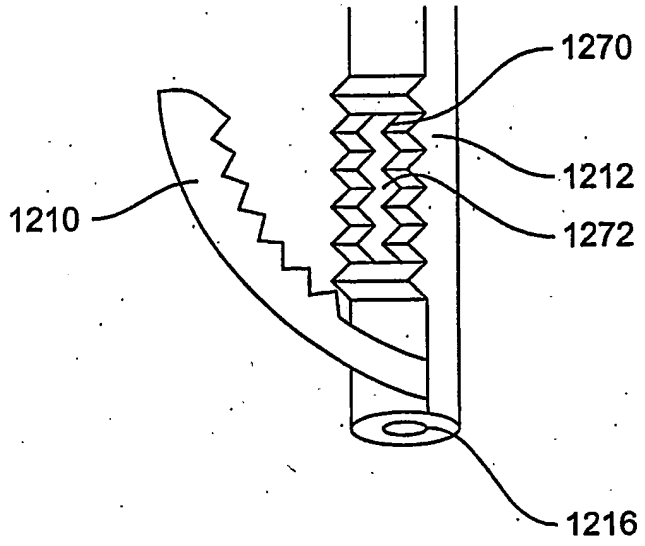

FIG. 90A

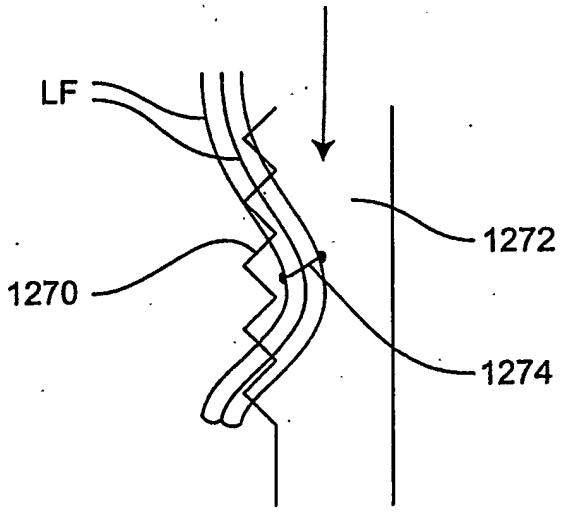

FIG. 90B

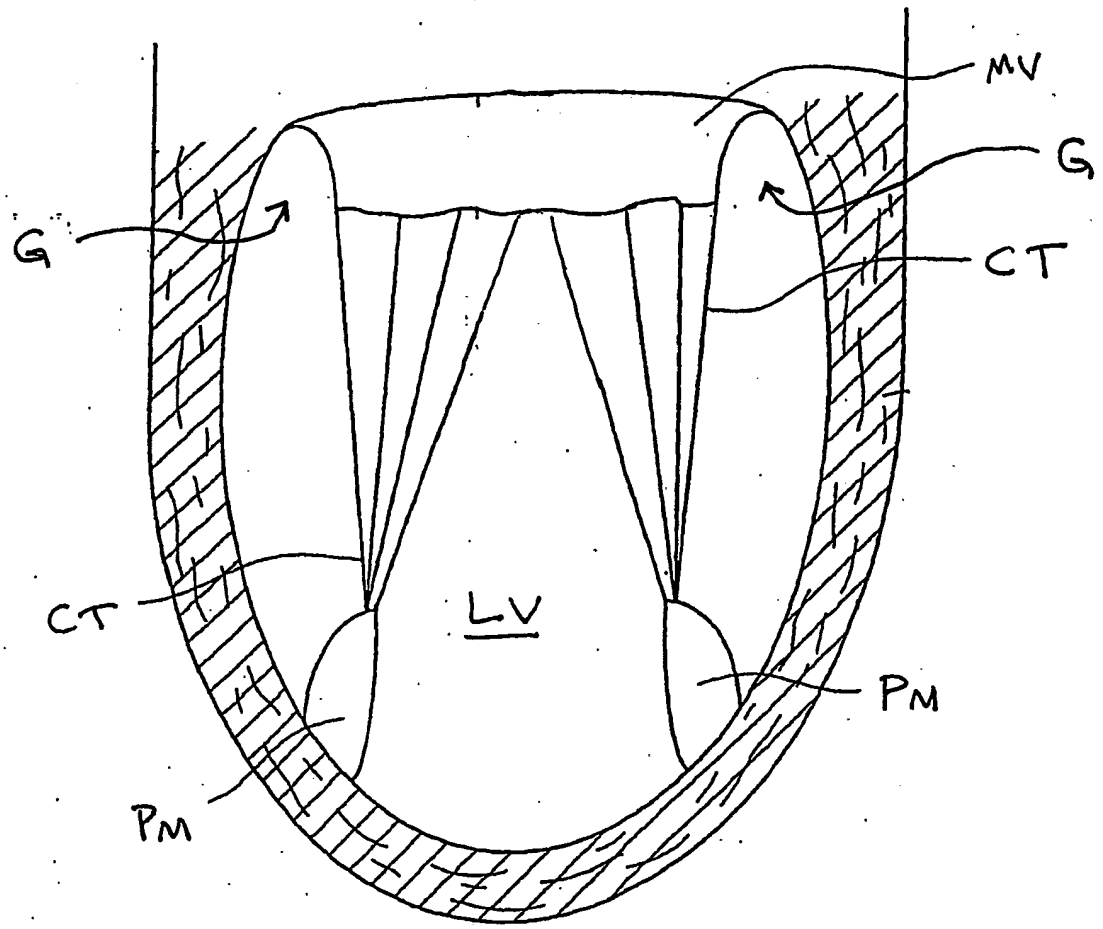

Figure 91

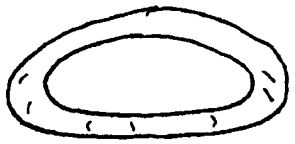

FIG 92A

FIG 92B

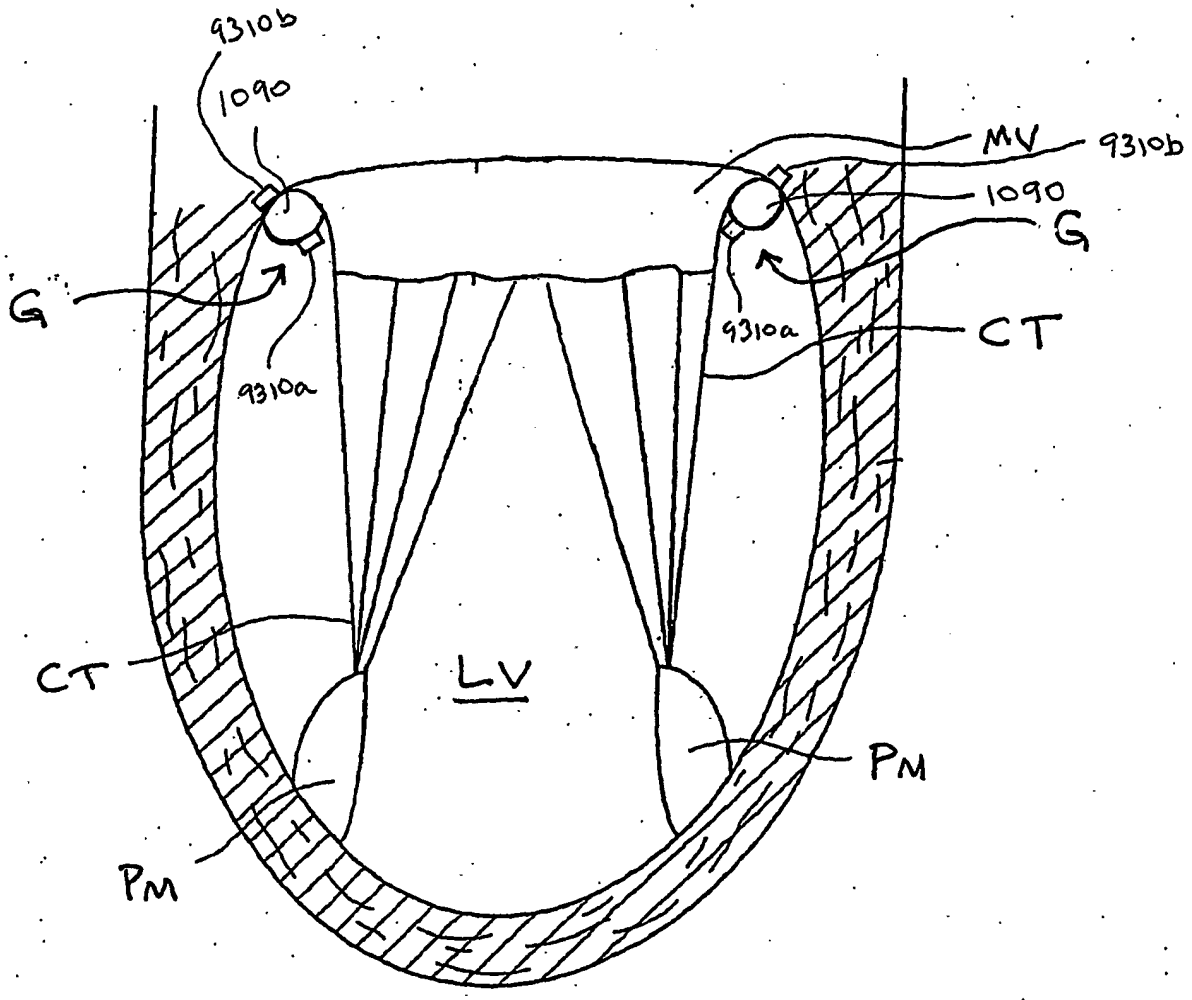

Figure 93

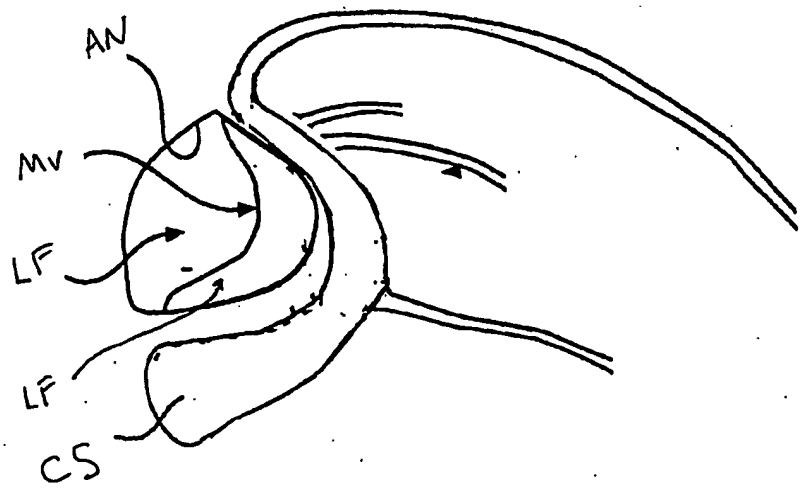

FIG. 94